Supreme Court, U.S.
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No. ——

In the Supreme Court of the United States

FRESENIUS USA, INC.
AND FRESENIUS MEDICAL CARE HOLDINGS, INC.,
Petitioners,

v.

BAXTER INTERNATIONAL, INC.
AND BAXTER HEALTHCARE CORPORATION,
Respondents.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

1. Does the Federal Circuit's practice of evaluating jury verdicts in patent cases by requiring a prevailing party to point to substantial evidence ***plus*** a detailed explanation by an expert witness of that evidence (a "substantial evidence plus explication" requirement) comport with this Court's precedents and the Constitution?

2. If the answer to Question 1 is yes, then in what circumstances should a requirement for substantial evidence plus explication apply?

RULES 14.1(b) AND 29.6 STATEMENT

All parties are identified in the caption of this petition. Petitioners Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. are for-profit corporations that manufacture hemodialysis machines for the treatment of various illnesses. All parent corporations and any publicly held companies that own 10 percent or more of the stock of any parent corporation are as follows: Fresenius Medical Care Management AG; Fresenius Medical Care AG & Co. KGaA; Fresenius Medical Care Beteiligungsgesellschaft mbH; Fresenius Medical Care Vermogensverwaltungs GmbH; Fresenius Medical Care US Vermogensverwaltungs GmbH and Co. KG; Fresenius US Zwei Vermogensverwaltungs GMBH and Co., KG; Fresenius Medical Care North America Holdings Limited Partnership; and Fresenius Securities, Inc.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners, Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. ("Fresenius"), respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The court of appeals' opinion (App., *infra*, at 1a-39a) is reported at 582 F.3d 1288 (Fed. Cir. 2009). The district court's opinion granting Baxter judgment as a matter of law (JMOL) and a new trial (App., *infra*, at 42a-71a) is reported at 2007 WL 518804 (N.D. Cal. Feb. 13, 2007), while the district court's order denying Fresenius' motion for summary judgment of invalidity (App., *infra*, at 72a-147a) is reported at 2006 WL 1343648 (N.D. Cal. May 16, 2006). The district court's order construing the claims of Baxter's patents (App., *infra*, at 148a-160a), was not reported but was entered on the docket on March 2, 2005 as Document No. 351 in the public files of the proceedings before the district court.

JURISDICTION

The court of appeals entered its judgment on November 18, 2009, by denying Fresenius' petition for rehearing en banc. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

"In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of

trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. Const. amend. VII.

STATUTORY PROVISIONS INVOLVED

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a).

"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6.

INTRODUCTION

This petition challenges the Federal Circuit's use of a special standard of review for jury verdicts that it, but no other circuit, has adopted. That special standard requires a prevailing party that wins a jury trial to defend its verdict by identifying substantial evidence in the record ***and also*** by showing that an

expert provided detailed explication of the evidence. The jury is not trusted to understand the substantial evidence on its own. The Federal Circuit's special "substantial evidence plus explication" rule extends beyond any standard applied by this Court or any other circuit. More particularly, the Federal Circuit in this case applied the rule to Fresenius' proof of obviousness, with the effect of circumventing this Court's holding in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2008), which found claims obvious as a matter of law using only common sense and the documentary record, without any need for expert explication.

The Federal Circuit's special standard suffers from two other fundamental problems for which this Court has repeatedly criticized that court. First, the standard is a patent-specific rule borne apparently of the Federal Circuit's belief that patent law is too complex for any jury to understand without expert assistance. Of course, other fields (*e.g.*, antitrust, product liability, *etc.*) are equally, if not more, complex in terms of technology and the law, and though experts are also common in those areas, their explanation of the evidence is not required when substantial evidence otherwise supports the verdict. Second, the special standard is a wooden rule, applied regardless of the complexity of the law or facts in a case—when this Court has repeatedly stressed the importance of flexibility in patent doctrine.

This is also an appropriate case in which to address the issue. While the Federal Circuit initially confined its "substantial evidence plus explication" rule to a narrow group of cases, this appeal represents a radical expansion of the standard, and

is in demonstrable conflict with the Court's *KSR* decision. Just as important, the claims of the patent that are appealed—ruled obvious by a jury, but non-obvious by the Federal Circuit based on its technical rule of proof rather than the merits—are overbroad and the type of patent claims that unnecessarily burden development of life-saving medical technologies and drive up the cost of healthcare. The case thus implicates the "special public interest considerations" addressed by three Justices in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124, 135 (2006), because overbroad patents "inhibit doctors from using their best medical judgment," "divert resources" from healthcare tasks to "the legal task of searching patent files," and "raise the cost of health care while inhibiting its effective delivery." 548 U.S. at 138. All of these factors counsel for review in this appeal.

STATEMENT

A. Baxter's Overbroad Patent Claims And The Prior Art

The Baxter patent claims are directed to an obvious combination of prior art devices, not to real innovation. Specifically, they address the idea of using touchscreens to replace traditional knobs and buttons for controlling hemodialysis machines.[1] Other types of medical devices had previously used touchscreens, and the jury found, based on

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[1] Hemodialysis machines filter the blood of toxins when a person's kidneys are unable to do so. C.A. A14239-40 (212-13); A14325-27 (483:3-84:9); A8257-75.

Fresenius' presentation of such systems (including bringing actual prior art hemodialysis machines into the courtroom) and documentation about such systems, that each asserted patent claim would have been obvious, and was thus invalid.

The claims at issue in this petition—claims 26-31 of U.S. Patent No. 5,247,434 ("the '434 patent")—add trifling features to the basic "dialysis machine plus touchscreen" idea. In particular, the claims recite the use of pumps in dialysis machines—though it is hardly inventive to use pumps with a machine whose central purpose is to circulate liquids to and from a patient. The claims are written in the so-called "means-plus-function" format of 35 U.S.C. § 112, paragraph 6, whereby a patentee can recite a claim element as a "means" for performing a function, and that element will be interpreted to cover the structures disclosed in the patent for performing the function plus equivalent structures.[2] For example, claim 26 recites a "means for delivering [a] dialysate

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[2] *See Applied Med. Res. Corp. v. United States Surgical Corp.*, 448 F.3d 1324, 1332 (Fed. Cir. 2006). Congress enacted this provision in response to the Court's decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), which held that patentees could not claim apparatuses in purely functional terms. Section 112, paragraph 6 gives patentees the convenience of drafting claims in functional terms, but then automatically imports the relevant structures into the claims. *See Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042 (Fed. Cir. 1993) (means-plus-function claims are limited "to the structure, material, or acts in the specification and their equivalents.").

to a dialysate compartment of a hemodialyzer."[3] The structure for this feature is nothing more than an ordinary pump. C.A. App. A61-62. Claim 30 recites an additional feature of a "means for delivering an anticoagulant to a patient, . . . ", and the relevant structure is a microprocessor and a stepper motor—*i.e.*, a computer-controlled pump that can push out liquid in small steps. C.A. App. A188.

At trial, Fresenius's expert witness testified that the prior art disclosed a hemodialysis machine with a computer and that all prior art hemodialysis machines had pumps. C.A. A20551; A20585; A20565-66. Baxter's expert witness admitted that the same prior art hemodialysis machine used the very type of pump the specification of the '434 patent says is capable of delivering a dialysate. C.A. A14576-77 (1131:22-93:8).

Baxter's own inventor admitted that: (1) every hemodialysis machine must have a means for controlling and circulating dialysate; (2) he was unaware of any hemodialysis machines that circulate dialysate without using a dialysate circuit; and (3) blood and heparin (an anticoagulant) pumps were old features of hemodialysis machines. C.A. A14399 (702:3-17). Prior art reference manuals that Fresenius placed in evidence, and that its expert testified about, disclosed the particular "stepper motor" required by Claim 30 and showed hemodialysis machines that pump blood and anticoagulant at predetermined rates using a motor-

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[3] Dialysate is a fluid that is used to filter the blood of toxins. All of the claims include this feature because claims 27-31 incorporate all the elements of claim 26.

powered syringe plunger that automatically infuses heparin. C.A. A19913-15; A20005; A20009.

Thus, the evidence concerning the content of the prior art established that the "pump" claims add nothing of substance. They simply claim functions that all prior art hemodialysis machines had to perform using structures that had long been in the prior art.

B. The District Court's Decision Overruling The Jury's Obviousness Findings

Fresenius brought this suit seeking a declaration that, among other things, Baxter's claims were invalid. The single issue tried to the jury was the validity *vel non* of the claims.[4]

The overriding issue at trial was whether it would have been obvious to use a touchscreen on a hemodialysis machine when touchscreens had been used with various other medical devices. The parties never contested whether a "means for delivering a dialysate," or whether a "means for delivering an anticoagulant," were in the prior art. That is because they add nothing of substance to prior art hemodialysis machines. After hearing all the evidence, including the expert testimony from both parties related to the pump–based elements, the jury returned a verdict in favor of Fresenius, finding all the claims asserted by Baxter to be invalid, and in particular, finding claims 26-31 to be invalid under

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[4] Fresenius stipulated before trial that its hemodialysis machines contained every element of the claims as construed by the district court.

35 U.S.C. § 103, for being nothing more than obvious variants of the prior art.

The District Court overruled this verdict in full. It did so despite the absence of any record evidence contradicting the jury's findings while holding that there was insufficient evidence to support a finding that the prior art contained the pump-based claim elements. *See, e.g.*, App., *infra*, at 57a-60a. Specifically, the District Court faulted Fresenius for failing "to identify any evidence given to the jury describing a microprocessor or a microprocessor with a blood pump performing the claimed function, *i.e.*, 'delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient.'" App., *infra*, at 56a (quoting the '434 patent). In essence, the court ruled that the jury's verdict was unsupported by substantial evidence because Fresenius had not gone through the documentary evidence page-by-page, but had instead relied on sworn expert testimony regarding an undisputed issue. The district court also held there was insufficient evidence to support the jury's implicit finding that the prior art disclosed the particular "stepper motor" required for performing the function of "delivering an anticoagulant" recited by Claim 30.

Finally, the district court held that the evidence concerning the content of the prior art and knowledge of ordinary skilled artisans lacked a "clear and particular showing, teaching, or motivation to combine the use of touchscreen technology with a hemodialysis machine." App., *infra*, at 61a. Relying on precedent regarding the law of obviousness decided before this Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398

(2007), it stated that the closest prior art reference "is an 'obvious to try' situation: it may have been obvious to try implementing a touchscreen interface together with numerous medical devices, including a hemodialysis machine, but the article in context merely suggests this might be a 'promising field of experimentation.'" 61a-62a (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988)).

C. The Federal Circuit's Decision Upholding Claims 26-31

The Federal Circuit reversed the district court (and thereby reinstated the jury verdict) on some claims, but affirmed the JMOL on claims 26-31 of the '434 patent—"though for somewhat different reasons than those articulated by the district court." 22a. The Federal Circuit did not take the position that the pump-based features were absent from the prior art that was in evidence, but instead that Fresenius failed to "identify[] the structure in the specification that corresponds to the means for delivering a dialysate" and for failing to "compare[] it to the structures in the prior art." 23a. Of course, it is the district court's responsibility to identify relevant structure in the patent as part of its claim construction process, not a party's. *See Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1350 (Fed. Cir. 2003) ("In construing a means-plus-function limitation, a court must identify both the claimed function and the corresponding structure in the written description for performing that function."). The Federal Circuit also rebuffed Fresenius for not "clearly disclos[ing], discuss[ing], and identify[ing] for the jury the supporting evidence upon which it was relying to prove that the claim limitation was present in the prior art." 23a. In

short, the Federal Circuit faulted Fresenius for its presentation of the evidence, but without disputing that the evidence was before the jury and that the jury was fully capable of understanding that the pumps in the prior art could be used in dialysis machines, as recited in Baxter's claims 26-31.

Implicitly recognizing the invalidity of the claims, but sticking with the court's special procedural rule, Circuit Judge Dyk, in concurring, referred to the "dubious validity" of the surviving claims and suggested that the district court should be open to staying the case in light of ongoing reexamination proceedings on the Baxter claims at the Patent & Trademark Office. 39a. This statement focuses the issue here precisely. The Federal Circuit was aware that, on the record evidence itself, the Baxter claims are invalid, but chose instead to expand its explication requirement in this case. Indeed, all claims asserted by Baxter in this litigation, including claims 26-31 of the '434 patent, stand rejected by the Patent & Trademark Office as unpatentable and have been appealed by Baxter, which is currently awaiting ruling from the Board of Patent Appeals & Interferences. The result here is an improper restraint on the marketplace that not only affects Petitioner but all marketplace participants.

The Federal Circuit, in making its holding, cited its prior decision in *Koito Manufacturing Co. v. Turn-Key-Tech,* LLC, 381 F.3d 1142 (Fed. Cir. 2004), where the court first expanded an old, but until then selectively-applied, rule that required expert explication of evidence in addition to presentation of the evidence itself to a jury. *Koito* in turn expanded on a line of cases that started with *Nestier v.*

Menasha Corp., 739 F.2d 1576, 1579 (Fed. Cir. 1984), where the Federal Circuit originated its test in the context of doctrine of equivalents infringement, which requires proof that each element of a patent claim is met by an accused product or process—the so-called "element-by-element" rule. As the Federal Circuit explained in *Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422 (Fed. Cir. 1989), special expert explication for each claim element was required because the court did not trust juries to otherwise apply the law properly:

> [I]f a jury is to rationally find all three elements of equivalence, it must be told what evidence establishes the equivalence of the claimed and accused devices as to each element. Otherwise, there is too much risk that the jury will simply compare the two inventions as to overall similarity . . . .

Id. at 1427. In the Federal Circuit's view, substantial evidence alone does not suffice because, in the absence of careful expert assistance, no reasonable jury can be trusted to follow the law provided to it in jury instructions.

It is this line of cases with which the present petition takes issue.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's requirement for expert explication on top of substantial evidence has no support in the law. While expert testimony can certainly be helpful, the Federal Circuit is wrong to assume that a reasonable jury cannot understand the law of obviousness or the basic concept of using

certain prior art pumps with touchscreen hemodialysis machines. The Federal Circuit's additional requirement, which robs juries of the right to determine difficult issues absent expert spoon feeding, is also inconsistent with this Court's decision in *KSR* and with the Seventh Amendment.

If explication is to be required in certain situations, those situations should be clearly defined. For example, before taking a verdict away from a jury, the party seeking to overturn the verdict must identify how, and a court must make an explicit determination that, the law or the technology is so complex that no reasonable jury could understand it without expert help.

I. THE FEDERAL CIRCUIT IS WRONG TO TAKE CASES AWAY FROM A JURY WHERE SUBSTANTIAL EVIDENCE IS PRESENT.

The Federal Circuit has never examined the rationale for its special rule requiring experts to explain substantial evidence in the record. The rule itself is not based on any precedent—the *Nestier* decision where the rule is said to have originated cites no case for the rule, and the follow-up *Lear Siegler* decision simply voices a fear that juries will improperly perform infringement analyses by looking at the invention and the accused product as a whole, rather than element-by-element as the infringement law requires. *See* 873 F.2d at 1427 ("there is too much risk that the jury will simply compare the two inventions as to overall similarity . . . ."). The *Lear Siegler* panel cited no evidence to support this paternalistic view. And of course, such challenges

for juries are not extraordinary, since juries are asked to separate issues in many areas of the law outside of patents.[5]

Indeed, the relevant academic research indicates that juries are fully competent to handle the vast range of patent issues. Empirical studies, in fact, indicate that the Federal Circuit's affirmance rate of judge and jury decisions is the same—78%. *See* Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black* Box, 99 Mich. L. Rev. 365, 397 (2000).

The expansion of the explication requirement from infringement proofs to obviousness proofs is also inconsistent with the Federal Circuit's own rationale for the rule, though the court has never recognized this problem. Specifically, while infringement determinations are ***not*** to be based on overall similarity, obviousness determinations are, *see* 35 U.S.C. § 103—so under the Federal Circuit's own understanding of the basis for its rule (*i.e.*, to avoid juries from looking at "overall similarity"), expert testimony should not be necessary to prevent a jury from ignoring the proper law on the issue of obviousness.

Aside from the inherent problems with the Federal Circuit's special rule, that rule is also

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[5] In the context of infringement proofs, the Federal Circuit has phrased its test as requiring "particularized testimony and linking argument." *See Lear*, 873 F.2d at 1425-27; *see also Aquatex Indus, Inc. v. Techniche Solutions, Inc.*, 479 F.3d 1320, 1329 (Fed. Cir. 2007); *Tex. Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996); *Malta v. Schulmerich Carillons*, 925 F.2d 1320, 1327 (Fed. Cir. 1991).

inconsistent with all other legal indicators. First, Baxter has not identified any circuit that has a rule like the Federal Circuit's patent-specific rule here, and indeed, even the Federal Circuit does not appear to apply the rule in its non-patent cases. *See also* Gregory D. Leibold, Comment, *In Juries We Do Not Trust: Appellate Review of Patent Infringement Litigation,* 67 U. Colo. L. Rev. 623, 660, n.207 (1996) (searching for, but not finding, a substantial evidence explication requirement in non-patent cases).[6] Thus, the "substantial evidence plus explication" requirement is a patent-specific rule that lacks any logical or legal basis, just like the Federal Circuit's former patent-specific injunction rule that was eliminated in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

The uniform practice of other circuits to require substantial evidence, but nothing more, is no doubt driven by this Court's case law that draws the line between judge and jury as one of substance, unrelated to the manner in which that substance is presented to the jury. *See Anderson v. Liberty Lobby*, 477 U.S. 242, 252 (1986). In fact, the Court has repeatedly addressed the "substantial evidence" standard, and has never suggested that something more is required, or even could be required to maintain a jury verdict.

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[6] The cases cited by Baxter below as requiring expert testimony were cases in which the expert testimony was itself the substantial evidence. In this case, the Federal Circuit did not assert that the record lacked substantial evidence, but instead focused on Fresenius' presentation of that evidence.

The Federal Circuit's practice of lessening the jury's role in deciding factual disputes also raises very real Constitutional issues. Specifically, the "substantial evidence" standard is synonymous with the "reasonable juror" standard, which in turn defines the Constitutional right to trial by jury rather than intervention by a court. *See id.* at 252 ("the judge must ask . . . whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented"); 9B C. Wright & A. Miller, *Federal Practice and Procedure* § 2524 at 268, n. 8 (citing substantial evidence standard as a "different term[]" that likely does not produce a different result); Black's Law Dictionary (8th Edition, 2004) (defining "substantial evidence" as "[e]vidence that a reasonable mind could accept as adequate to support a conclusion; . . . ."). The Federal Circuit's special rule crosses that line, and in turn removes a right—guaranteed in the Seventh Amendment—to have issues that are supported by substantial evidence placed wholly in the hands of the jury.

Last but certainly not least, the Federal Circuit's expansion of its special test from infringement to obviousness is contrary to this Court's decisions in *KSR v. Teleflex* and the seminal modern obviousness decision, *Graham v. John Deere*, 383 U.S. 1 (1966). In *KSR*, the district court granted summary judgment of obviousness, the Federal Circuit vacated, and this court reversed, reinstating the summary judgment of invalidity. In doing so, the Court made no mention of expert testimony. Thus, without the need for explication that the Federal Circuit found necessary in the current case, this Court ruled the claims invalid as a matter of law (not merely supported by substantial evidence of obviousness). The Court also invalidated the patents

in *Graham*, without the need for any explication from the experts retained by the parties who had challenged their validity, *see* 383 U.S. at 19-37. Both decisions—which are premised on common sense rather than any need for experts—are inconsistent with the Federal Circuit's new requirement for expert explication in addition to substantial evidence.

Similarly, common sense would lead anyone to conclude that they could use a pump with a hemodialysis machine since the whole point of the machine is to circulate fluids. Baxter admits prior art hemodialysis machines had to have heparin delivery systems. And the prior art in evidence showed the more specific use of computer-controlled stepper motors for moving heparin, a well-known anticoagulant, so it would have been no great leap for the jury to conclude—again, using its own common sense—that a skilled artisan would have used the same structure for anticoagulant. Thus, this case, which borders on obviousness as a matter of law, does not lack for substantial evidence, and certainly could have been understood by a reasonable juror without expert assistance. In short, the effect of applying the Federal Circuit's special rule here was to wipe out the results this Court sought to achieve in *KSR*.

II. THE FEDERAL CIRCUIT'S SPECIAL RULE—IF IT IS TO EXIST AT ALL—SHOULD BE CAREFULLY CONFINED.

The Court should grant *certiorari* even if it concludes that there is a place in the patent law for the special explication requirement. That is because

the Federal Circuit's test must be carefully limited—both as a matter of logic and to keep it consistent with this Court's precedent. In particular, additional expert explication should be required only when the losing party at trial has established that no reasonable jury could have understood the law or technology absent explanation from an expert. A court applying the rule should also be required to make such a finding explicitly and explain the basis for the finding so that it could be reviewed on appeal.

Such limits are necessary to prevent courts from invading the jury's province, contrary to the Seventh Amendment. By forcing an explanation of why no reasonable jury would be able to understand the law or technology, such a test would be consistent with the "reasonable jury" standard for judgment as a matter of law that is part and parcel of the Constitution. Moreover, limiting the application of the rule only to cases in which no reasonable juror could understand the law or technology without help is one way to make application of the rule consistent with *KSR* and *Graham*.

Regardless, though, this case does not meet any such standard. The law of obviousness is not too complex for a jury—and it certainly did not stand in the way of declaring the claims in *KSR* and *Graham* invalid despite the lack of expert testimony. And while hemodialysis machines certainly can be technically complex, the issue here is not with the technically complex aspects of the machines, but simply with whether the use of a pump, or a computer-controlled stepper-motor pump, with a touchscreen hemodialysis machine would have been obvious. Given that pumps have long been central to hemodialysis machines, and that a stepper-motor

pump was disclosed in the prior art introduced at trial, a reasonable jury certainly could have understood the technology here, just as well as it could have understood the technology in *KSR* (even though vehicle control systems in cars, the more general technology at play in *KSR*, can also be technically complex)

In affirming the district court's decision to set aside the jury's verdict as to Claims 26-31, the Federal Circuit shifted the focus from the question of whether it would have been obvious to combine a touchscreen with a hemodialysis machine having pumps to whether evidence on an undisputed issue had been adequately explained to a jury. The result was the failure to invalidate a patent that the Patent Office should never have granted in the first place, as an ongoing reexamination in its final stages at the Patent & Trademark Office itself has confirmed.

III. THIS IS AN APPROPRIATE CASE FOR REVIEW.

The issue in this case is core to patent law and is ripe for review. It is core because defendants in almost all patent trials seek to have the jury determine whether the patent claims are no different than the prior art or are at most obvious over the prior art. Thus, the standard of review in such cases will continue to be important on appeal.

The issue is ripe because the holding here marks a new and broad expansion of a long-applied (though previously narrowly-applied) rule in a way that seriously undercuts the Court's decision in *KSR*. As in *KSR*, no more time is needed to see where the

Federal Circuit will go with this rule—it has applied the rule for two decades and is now expanding it.

Moreover, the issue has great public importance because Baxter has used its patents in an attempt to interfere with Fresenius' efforts to provide medical care to patients in great need of hemodialysis, and to drive up the costs of hemodialysis for those patients through its demands for an extravagant damages award. The Justices who dissented from the Court's decision not to reach the merits in *Labcorp* well explained the problem in such situations (548 U.S. at 138):

> [S]pecial public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery.

Such concerns extend well beyond hemodialysis machines, as medical devices and other healthcare-related patents are litigated every day subject to the Federal Circuit's special rule. If substantial evidence exists in the record that those patents are invalid, they should not be left to stand. Indeed, the harmful

effect of such overbroad patents has been confirmed in the academic literature. *See* M. Boldrin & D. Levine, AGAINST INTELLECTUAL MONOPOLY 73-77, 89-92, 184-187, 214-218, 238, 246 (2009) (describing dramatic increase in patent grants over last decade resulting in a "patent thicket" harmful to innovation); L. Lessig, THE FUTURE OF IDEAS 205-217 (2001) (describing negative impact of broad patent protection on innovation; "we should be most concerned when existing interests use the legal system to protect themselves against innovation"); L. Branstetter, Do Stronger Patents Induce More Local Innovation?, 7 J. INT'L ECON. L. 359, 369 (2004) ("well-structured research projects conducted by competent scholars" have "failed to find" innovation benefits from expanded patent monopolies).

With public focus properly placed on the cost of delivering healthcare to Americans, this is a particularly good time to address the role of patents in affecting such costs, and the proper rules for distinguishing meritorious inventions from minor, unpatentable improvements over the art.

CONCLUSION

For the foregoing reasons, the Court should grant *certiorari* in order to impose a proper standard of review for jury verdicts on the Federal Circuit.

Respectfully submitted.

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February 16, 2010

APPENDIX A

United States Court of Appeals for the Federal Circuit

*Revised September 14, 2009

2008-1306, -1331

FRESENIUS USA, INC. and
FRESENIUS MEDICAL CARE HOLDINGS, INC.,

Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,

Defendants-Cross Appellants.

Juanita R. Brooks, Fish & Richardson P.C., of San Diego, California, argued for plaintiffs-appellants. With her on the brief were Michael E. Florey, Mathias W. Samuel and Deanna Reichel, of Minneapolis, Minnesota, and Robert E. Hillman, of Boston, Massachusetts.

William F. Lee, Wilmer Cutler Pickering Hale and Door LLP, of Boston, Massachusetts, argued for defendants-cross appellants. With him on the brief were Bharat R. Ramamurti; William G. McElwain

and Jonathon G. Cedarbaum, of Washington DC. Of counsel on the brief were Michael J. Abernathy and Sanjay K. Murthy, K & L Gates LLP, of Chicago, Illinois.

Appealed from: United States District Court for the Northern District of California.

Judge Sandra Brown Armstrong

*Correction of law firm name.

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC. and
FRESENIUS MEDICAL CARE HOLDINGS, INC.,

Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,

Defendants-Cross Appellants.

Appeals from the United States District Court for the Northern District of California in case no. 03-CV-1431, Judge Saundra Brown Armstrong.

DECIDED: September 10, 2009

Before NEWMAN, GAJARSA, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Concurring opinions filed by Circuit Judge NEWMAN and Circuit Judge DYK.

GAJARSA, Circuit Judge.

In this patent infringement case, Plaintiffs Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") appeal and Defendants Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter") cross appeal from the final judgment of the United States District Court for the District of California, which was based on findings that Fresenius infringed claims of three patents asserted by Baxter—U.S. Patent Nos. 5,247,434 ("the '434 patent"), 5,744,027 ("the '027 patent"), and 6,284,131 ("the '131 patent")—all of which disclose and claim a hemodialysis machine integrated with a touch screen user interface. Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc., No. 03-CV-1431 (N.D. Cal. Feb. 12, 2007) ("JMOL Opinion"). We affirm in part, reverse in part, vacate in part, and remand for further proceedings consistent with this opinion.

BACKGROUND

I. The Technology and Patents

When a person's kidneys fail to function properly, a hemodialysis machine can function in place of the kidneys to cleanse the blood of toxins. During hemodialysis, the person's blood is pumped through a hemodialysis machine, which contains a dialysate—a solution formulated to draw toxins out of the blood. Inside the machine, the blood is separated from the dialysate by a semi-permeable membrane that allows toxins to pass from the blood into the dialysate. Because it is important to ensure that tox-

ins are removed without inadvertently filtering essential nutrients out of the blood, the hemodialysis machine must facilitate the monitoring and control of numerous parameters.

All of the patents at issue derived from a parent patent application filed in 1991, and all of the relevant claims are directed to a hemodialysis machine integrated with a touch screen user interface. At the time the parent application was filed, touch screens were known and had been used on other medical devices, such as a heart-lung machine, but a touch screen had not been integrated with a hemodialysis machine. The System 1000, which embodies the patents at issue, was introduced in 1991 and was a commercial success.[1] In 1998, Fresenius introduced the alleged infringing device, a hemodialysis machine with a touch screen interface called the 2008K machine.

A. The '027 Patent

The only '027 patent claim at issue in this appeal is claim 11, which is dependent on claim 10, which is in turn dependent on claim 7. Claim 7 reads:

> A kidney dialysis machine, comprising:
>
> (a) a dialysate pump for circulating dialysate at a dialysate conductivity through a dialysate

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[1] Althin filed the relevant patent applications and introduced the System 1000. Baxter purchased Althin and the patents at issue in March 2000.

> circuit including a dialysate compartment for a dialyzer; and
>
> (b) a controller operable to receive non-conductivity data concerning a particular selection of dialysate to be circulated and to calculate from the data an expected conductivity reading of the dialysate.

'027 Patent col.36 ll.14–21. Dependent claim 11 additionally requires only a "data input device" that "comprises a touch screen." Id. at col.36 l.32–33. The additional limitation of claim 10 is not at issue in this appeal.

B. The '131 Patent

Regarding the '131 patent, independent claim 1 and claims 2, 3, and 13–16, which are dependent on claim 1, are at issue in this appeal. Claim 1 reads:

> A hemodialysis apparatus, comprising:
>
> (a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

> (b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface
>
> comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis apparatus, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.

'131 Patent col.36 ll.1–21. Claim 14 additionally requires only that "the touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." Id. at col.36 ll.64–67. Claim 16 additionally requires that "the user/machine interface is operable to require the user to verify a parameter after a value of the parameter is selected." Id. at col.37 ll.4–6. The additional limitations recited in claims 2, 3, 13, and 15 were not argued on appeal.

C. The '434 Patent

Regarding the '434 patent, independent claim 26 and claims 27–31, which are dependent on claim 26, are at issue in this appeal. Claim 26 reads:

> A hemodialysis machine comprising:
>
> (a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and
>
> (b) a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

'434 Patent col.40 ll.29–42. Dependent claims 27–31 include additional limitations, but only the additional limitation in claim 30 is relevant to this appeal. That limitation requires a "means for delivering an anticoagulant to a patient wherein the touch screen further provides an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery." Id. at col.40 ll.61–64.

II. Litigation Background

Fresenius initially filed suit against Baxter in 2003, seeking a declaratory judgment that the '027, '131, and '434 patent claims are invalid and not in-

fringed by Fresenius's hemodialysis machines.[2] Baxter counterclaimed, alleging that Fresenius infringes claims 7, 11, and 14–16 of the '027 patent; claims 1–3 and 13–16 of the '131patent; and claims 26–31 of the '434 patent. On Baxter's motion, the district court granted partial summary judgment that Fresenius infringes claim 1 of the '131 patent and claim 26 of the '434 patent. Baxter continued to allege that Fresenius infringes the other asserted claims, and Fresenius continued to allege that all asserted claims are invalid. Following claim construction, Fresenius stipulated that it infringes Baxter's remaining asserted claims. A jury trial on validity followed, and the jury found claims 7 and 14–16 of the '027 patent invalid as anticipated and all asserted claims invalid as obvious.

The district court determined that substantial evidence does not support the jury's obviousness verdict and granted Baxter's motion for judgment as a matter of law ("JMOL") that its asserted patent claims are not invalid as obvious. Namely, the district court found that Fresenius had not presented evidence that specified limitations of claim 11 of the '027 patent, claims 1 and 14 of the '131 patent, and claims 26–31 of the '434 patent were present in the prior art. JMOL Opinion, slip op. at 8–13, 18–19. In addition, the district court found that Fresenius did not present substantial evidence of a motivation to combine the elements of the prior art to produce the invention claimed in the '131 and '434 patents. Id. at 13–16. The court did not evaluate the jury's findings that claims 7 and 14–16 of the '027 patent are inva-

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[2] The original filings included two additional patents–neither of which is relevant to this appeal.

lid as anticipated, stating that Baxter had not challenged the anticipation verdict. Id. at 6 n.1.

After a jury trial on damages, the jury awarded Baxter a total of $14,266,000 in damages, $91,000 of which was attributable to unpatented disposable products. The district court, after considering the four factors articulated in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006), concluded that injunctive relief was appropriate and permanently enjoined Fresenius. Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc., No. 03-CV-1431, slip. op. at 8–10 (N.D. Cal. March 21, 2008) ("Injunction Order"). The district court ordered that the injunction take effect on January 1, 2009, because Fresenius indicated it could develop a non-infringing machine by that date. Id. at 8–9. The district court also ordered Fresenius to pay an ongoing royalty of 10% of the sales price for any infringing machines sold before January 1, 2009, and a royalty of 7% of the sales price for all disposable products linked to infringing machines that were sold from November 7, 2002, until the patents expire. Id. at 9–10. The district court imposed the royalty rates without explaining the bases for its calculations.

Fresenius appeals the district court's grant of JMOL, entry of a permanent injunction, royalty award, and constructions of specified claim terms. Baxter cross appeals the jury's determination that the asserted '027 patent claims are invalid as anticipated. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

Following the procedural law of the Ninth Circuit, we review the district court's grant or denial of JMOL de novo. Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed. Cir. 2009) (citing Theme Promotions, Inc. v. News Am. Mktg. FSI, 546 F.3d 991, 999 (9th Cir. 2008)); see also Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1149 (Fed. Cir. 2004) (reviewing without deference JMOL decisions of a district court in the Ninth Circuit). "The party requesting the JMOL . . . must show that substantial evidence did not support the jury's findings, where substantial evidence is 'such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review.'" Koito, 381 F.3d at 1149 (quoting Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1563 (Fed. Cir. 1996)); see also Revolution Eyewear, 563 F.3d at 1370–71.

As we have explained, "[t]his court reviews a jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001). Where, as here, the jury made no explicit factual findings regarding obviousness, we must determine whether the implicit findings necessary to support the verdict are supported by substantial evidence. Upjohn Co. v. Mova Pharm. Corp., 225 F.3d

1306, 1310 (Fed. Cir. 2000). "[T]he verdict of obviousness must be supported by facts of (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) any objective indicia such as commercial success or long-felt need." Id.

Each patent claim is presumed valid, and as the party contending that the asserted claims are invalid, Fresenius was required to prove invalidity of each claim by clear and convincing evidence. See 35 U.S.C. § 282; Lisle Corp. v. A.J. Mfg. Co., 398 F.3d 1306, 1316 (Fed. Cir. 2005). Thus, in reviewing the jury's verdict, "we must determine whether the jury had substantial evidence upon which to conclude that [the party alleging invalidity] met its burden of showing invalidity by clear and convincing evidence." Koito, 381 F.3d at 1149.

In this appeal, we also consider the district court's entry of a permanent injunction and royalty award. We review the district court's grant of a permanent injunction for abuse of discretion. Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1379 (Fed. Cir. 2008); see also eBay, 547 U.S. at 391. Regarding the district court's royalty award, "we review the trial court's determinations for erroneous conclusions of law, clearly erroneous factual findings, and clear errors of judgment amounting to an abuse of discretion." Mitutoyo Corp. v. Cent. Purchasing, LLC, 499 F.3d 1284, 1292 (Fed. Cir. 2007).

II. Baxter's Cross Appeal Regarding Anticipation of Claim 7 of the '027 Patent

As the sole issue in its cross appeal, Baxter asserts that substantial evidence does not support the jury's finding that claim 7 of the '027 patent is invalid as anticipated. By failing to properly raise that argument before the district court, Baxter has waived it, and we decline to consider it. See Golden Bridge Tech., Inc. v. Nokia, Inc., 527 F.3d 1318, 1323 (Fed. Cir. 2008) (declining to consider a new argument the party could have raised before the district court); Sw. Software, Inc. v. Harlequin Inc., 226 F.3d 1280, 1290 (Fed. Cir. 2000) ("Failing to properly move for JMOL at the close of the evidence precludes a challenge to the sufficiency of the evidence underlying fact findings."); Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1426 (Fed. Cir. 1997) (declining to consider a novel infringement argument raised on appeal).

In Baxter's Rule 50(a) motion for JMOL and Rule 50(b) renewed motion for JMOL, Baxter only briefly mentioned the jury's anticipation verdict, and in each motion, Baxter relegated its discussion of that verdict to a single footnote. In its Rule 50(a) motion, Baxter merely stated that "[t]o preserve its rights, Baxter also moves for JMOL on Fresenius' defense that the Seratron System anticipates the asserted claims of the '027 patent because Fresenius has failed to prove that System is prior art with sufficient corroborating evidence." J.A. at 21588. Baxter provided no further explanation in the Rule 50(a) motion and did little to develop the anticipation argument in its Rule 50(b) motion. In that motion, also in a footnote, Baxter stated that it "renews its JMOL

on Fresenius' defense that the Seratron System anticipates and/or renders obvious the remaining asserted claims of the '027 Patent," and then provided a minimal explanation regarding how "Fresenius failed to prove by clear and convincing evidence that that Seratron System is prior art with sufficient corroborating evidence."

On appeal, Baxter argues that the Seratron System lacks two of the required claim limitations because "it is not operable to receive non-conductivity data concerning a particular selection of dialysate, and it does not use non-conductivity data to calculate an expected conductivity reading." Cross Appellant's Rep. Br. at 5–6. Baxter asserts that its limited statements to the district court preserved those arguments for appeal, but we disagree. Before the trial court, Baxter argued that it is entitled to JMOL because Fresenius failed to prove that the Seratron System is prior art—Baxter did not argue that the Seratron System lacked specified claim limitations. Contrary to Baxter's assertions, one specific challenge to an anticipation finding does not preserve all possible challenges to that finding. If a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal, and we do so here. See CBOCS W., Inc. v. Humphries, 128 S. Ct. 1951, 1963 n.2 (2008) (declining to consider a claim while noting the appellate court had deemed that claim waived because it was presented as "only a skeletal argument" to the district court) (citing Humphries v. CBOCS W., Inc., 474 F.3d 387, 407 (7th Cir. 2007)); Golden Bridge Tech., 527 F.3d at 1323 ("This is an appellate court and as such we abide by the general

rule that new arguments will not be decided in the first instance on appeal."); SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1320 (Fed. Cir. 2006) (deeming an argument waived because it was not presented as a developed argument in the opening brief); Sage Prods., 126 F.3d at 1426 ("With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party's new theories, lodged first on appeal. If a litigant seeks to show error in a trial court's overlooking an argument, it must first present that argument to the trial court.").

Moreover, the new anticipation argument Baxter presents on appeal includes factual assertions regarding the information contained in the Seratron manual. See Cross Appellant's Rep. Br. at 7–15. Fresenius contests those factual assertions, arguing that the technical statements in the Seratron manual cannot be interpreted in the manner proposed by Baxter. See Appellant's Rep. Br. at 18–20. Thus, the parties present a new factual dispute on appeal. Such a factual dispute should have been presented to the district court for its consideration in the first instance.

For the foregoing reasons, we conclude that Baxter did not properly present its argument regarding the claim 7 anticipation verdict to the district court, and thus, Baxter has waived that argument.

III. Obviousness

The district court determined that Fresenius failed to present substantial evidence that various non-touch-screen limitations of the asserted claims

were present in the prior art. The district court also found that Fresenius did not present substantial evidence of a motivation to combine the elements of the prior art to achieve the invention claimed in the '131 and '434 patents. Fresenius argues that the non-touch-screen limitations in the asserted claims were standard in prior art hemodialysis machines and that it presented substantial evidence of such to the jury. Baxter contends the asserted claims are nonobvious, or at a minimum, that Fresenius failed to meet its burden of proving invalidity by clear and convincing evidence. For the following reasons, we reverse the district court's grant of Baxter's JMOL motion, except as to claims 26–31 of the '434 patent.

A. Claim 11 of the '027 Patent

Because claim 11 is dependent on claim 7, it includes all limitations recited in claim 7. The district court determined that Fresenius had not presented any testimony regarding the obviousness of claim 7, and thus concluded that Fresenius necessarily failed to demonstrate that all limitations of claim 11 were in the prior art. JMOL Opinion, slip op. at 19. Specifically, the district court determined that because Mr. Causey—Fresenius's only expert witness to testify that claim 11 is obvious—did not discuss the claim 7 limitations, Fresenius had failed to meet its burden of proving by clear and convincing evidence that claim 11 is obvious. Id. We disagree.

As Fresenius notes, although Mr. Causey did not discuss the claim 7 limitations, Mr. Ragsdale, another expert witness for Fresenius, had previously discussed those limitations when he testified that

claim 7 is invalid as anticipated. In determining whether Fresenius presented substantial evidence to support the jury's verdict that claim 11 is obvious, we must consider all evidence that was before the jury and draw all reasonable inferences from that evidence in the light most favorable to Fresenius. See Koito, 381 F.3d at 1149. From Mr. Ragsdale's testimony, a reasonable jury could conclude that all limitations of claim 7 were present in the prior art. Claim 7 is divided into elements (a) and (b), and Mr. Ragsdale separately testified about each element, explaining how each was present in the prior art Seratron machine. J.A. at 14342–43. Fresenius also offered the Seratron's operating manual. Thus, when the jury was assessing the obviousness of dependent claim 11, it could reasonably conclude that all limitations of claim 7 were in the prior art based on Mr. Ragsdale's testimony.

Baxter argues that Fresenius failed to carry its burden because it did not properly connect all of the evidence regarding the obviousness of claim 11, namely because Mr. Causey never referred to Mr. Ragsdale's testimony. Cross Appellant's Br. at 40. That argument fails. Although it would have been advisable for Fresenius to ensure that Mr. Causey discussed all limitations of claim 11 when he testified regarding the obviousness of that claim, Fresenius was not required to do so. When, as here, the question of obviousness is submitted to the jury, we must review the jury's implicit factual findings for substantial evidence. Upjohn Co., 225 F.3d at 1310. Here, the jury implicitly found that all limitations of claim 7 were present in the prior art, and as explained above, substantial evidence supports that finding. Thus, a reasonable jury could conclude that

the non-touch-screen limitations of claim 11 were in the prior art by considering Mr. Causey's testimony in combination with Mr. Ragsdale's testimony and the Seratron manual. Because substantial evidence supports the jury's implicit finding, JMOL was inappropriate.

B. Claims 1–3 and 13–16 of the '131 Patent

On appeal, the parties limit their arguments to element (a) of claim 1 and specified additional limitations of claims 14 and 16.

1. Element (a) of Claim 1

Element (a) of claim 1 requires:

> a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit.

'131 Patent col.36 ll.1–8. The district court concluded that substantial evidence does not support the jury's verdict because Mr. Causey, Fresenius's expert who testified that claim 1 is obvious, did not specifically analyze element (a). Because Mr. Causey's "testimony did not analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim," the district court

determined that Fresenius had not met its burden of proving that claim 1 is invalid. JMOL Opinion, slip op. at 13. Because all the asserted claims of the '131 patent contain the element (a) limitation, the district court granted JMOL for all of the asserted claims. We disagree with the district court.

Element (a) is written in Markush form, such that the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art. See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (holding a claim invalid as anticipated when it claimed compounds in Markush form and a prior art reference disclosed one of the claimed compounds); In re Skoll, 523 F.2d 1392, 1397 (CCPA 1975); see also Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). Thus, a prior art device discloses element (a) if it contains a dialysate-delivery system for supplying dialysate to a hemodialyzer comprising only a dialysate-circulation unit (or any one of the other three listed alternatives).

It is clear that the prior art disclosed a hemodialysis machine containing a dialysate-circulation unit. Mr. Kelly, Baxter's witness, admitted and agreed that all hemodialysis machines—which the jury could reasonably presume would include those in the prior art—must have "some way of circulating the dialysate through a dialysate circuit." J.A. at 14399. In addition, Mr. Ragsdale testified that in his opinion, "the Seratron system includes a dialysate pump for circulating dialysate . . . through a circuit

including a dialysate compartment for a dialyzer." J.A. at 14342. Finally, Mr. Causey testified that the limitations of element (a) of the '131 patent are present in the CMS 08 prior art hemodialysis machine. Based on the totality of the testimony presented by Messrs. Kelly, Ragsdale, and Causey, the jury could reasonably conclude that the limitations of element (a) were known in the prior art. Specifically, the jury could conclude that the prior art contained a hemodialysis machine with a dialysate-delivery system that supplies dialysate to a hemodialyzer and comprises a dialysate-circulation unit. Because substantial evidence supports the jury's finding, JMOL was inappropriate.

2. Claim 14

Claim 14 of the '131 patent depends from claim 1 and adds one additional limitation: "wherein the touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." '131 Patent col.36 ll.64–67. Although the district court noted that the manual for the Cobe C3 prior art machine—which was in evidence and had been submitted to the jury—disclosed "an indicium corresponding to a time-variable hemodialysis parameter," the district court concluded that Fresenius failed to present any evidence that the "plurality of indicia" limitation of claim 14 was present in the prior art. JMOL Opinion, slip op. at 8–9. We disagree.

Mr. Causey testified, using an explanatory demonstrative, that the inventors of the prior art Cobe C3 machine had provided for more than one

time-variable parameter. The demonstrative indicated that the prior art machine allowed for multiple indicia, each corresponding to a different time-variable hemodialysis parameter. The jury could have reasonably credited Mr. Causey's testimony and concluded that the relevant limitation was present in the prior art Cobe C3 machine. Because substantial evidence supports the jury's implicit finding that the plurality of indicia limitation existed in the prior art, JMOL was inappropriate.

3. Claim 16

Baxter additionally asserts that Fresenius failed to demonstrate that the following limitation of claim 16 existed in the prior art: "the user/machine interface is operable to require the user to verify a parameter after a value of the parameter is selected." '131 Patent col.37 ll.4–6. That argument is unpersuasive. Fresenius's expert testified that the CMS 08 prior art machine contains the limitation described in the claim, referring specifically to a page of the CMS 08 manual that supports the testimony. J.A. at 14455, 19935. Thus, substantial evidence supports the jury's implicit finding that the claim limitation at issue existed in the prior art.

C. Claims 26–31 of the '434 Patent

Claims 26–31 contain means-plus-function limitations, and all require a "means for delivering the dialysate to a dialysate compartment of a hemodialyzer." '434 Patent col.40 ll.33–35. The district court granted Baxter's motion for JMOL of no inva-

lidity based in part on its conclusion that Fresenius failed to prove that the means for delivering dialysate limitation was present in the prior art. We agree, though for somewhat different reasons than those articulated by the district court. Namely, Fresenius failed to present any evidence—let alone substantial evidence—that the structure corresponding to the means for delivering dialysate limitation, or an equivalent thereof, existed in the prior art.

It is firmly established in our precedent that a structural analysis is required when means-plus-function limitations are at issue; a functional analysis alone will not suffice. See, e.g., CytoLogix Corp. v. Ventana Med. Sys., 424 F.3d 1168, 1178 (Fed. Cir. 2005) ("To establish infringement under § 112, ¶ 6, it is insufficient for the patent holder to present testimony 'based only on a functional, not a structural, analysis.'" (quoting Alpex Computer Corp. v. Nintendo Co., 102 F.3d 1214, 1222 (Fed. Cir. 1996))). Just as a patentee who seeks to prove infringement must provide a structural analysis by demonstrating that the accused device has the identified corresponding structure or an equivalent structure, a challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure—or an equivalent—was present in the prior art. See In re Donaldson Co., 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc) ("[W]e hold that paragraph six applies regardless of the context in which the interpretation of means-plus-function language arises, i.e., whether as part of a patentability determination in the PTO or as part of a validity or infringement determination in a court."); see also McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1361 (Fed. Cir. 2001) (Michel, J., dis-

senting) ("Of course, in the context of a means-plus-function claim, the invalidating prior art must disclose not simply a means for achieving the desired function, but rather the particular structure recited in the written description corresponding to that function, or an equivalent thereof.").

Here, Fresenius neither identified the structure in the specification that corresponds to the means for delivering dialysate nor compared it to the structures present in the prior art. See CytoLogix, 424 F.3d at 1178 ("Here, CytoLogix failed to identify the structure in the specification that is the 'temperature controller means' and compare it to the structure of the accused device. Accordingly, because CytoLogix failed to present substantial evidence of infringement of claim 13 of the '693 patent, the jury verdict of infringement of claim 13 must be reversed."). At most, the evidence of record supports a finding that some structures that could perform the claimed function existed in the prior art. Under our precedent, it is clear that such a finding is insufficient. Thus, as in CytoLogix, the jury's verdict as to claims 26–31 cannot stand.

We note also that there is an additional reason for affirming the district court's grant of JMOL regarding dependent claim 30, which requires a "means for delivering an anticoagulant to a patient." The district court instructed the jury that the corresponding structure is a microprocessor and stepper motor. Fresenius USA, Inc. v. Baxter Int'l, Inc., No. 03-1431, at 21 (N.D. Cal. July 5, 2006) (Dkt. No. 825) ("Jury Instructions"). Because Fresenius failed to present any evidence that the required stepper motor structure existed in the prior art, the district court correctly granted JMOL. Fresenius has cited no tes-

timony wherein any witness discussed a "stepper motor." Fresenius contends that the Cobe C3 manual, which was submitted to the jury, discloses the necessary structure, but notably, Fresenius has cited no manual pages that reference a "stepper motor." After independently reviewing the record, this court notes that the CMS 08 manual briefly mentions a "stepper motor" but does not discuss that structure in the context of the claimed function—delivering an anticoagulant. Moreover, even if the CMS 08 manual disclosed a stepper motor for delivering an anticoagulant, it was Fresenius's burden to clearly disclose, discuss, and identify for the jury the supporting evidence upon which it was relying to prove that the claim limitation was present in the prior art. See Koito, 381 F.3d at 1151 (holding that a challenger failed to meet its burden of proving a prior art reference anticipated the patent claims when it "failed to provide any testimony or other evidence that would demonstrate to the jury how that reference met the limitations of the claims"). Here, as with the means for delivering dialysate limitation discussed above, the evidentiary burden of proof cannot be carried without clearly identifying the corresponding structure in the prior art. Thus, substantial evidence does not support the jury's implicit finding that the prior art contained a stepper motor means for delivering an anticoagulant, and the district court correctly granted JMOL.

For the foregoing reasons, we affirm the district court's grant of JMOL as to claims 26–31 of the '434 patent.

D. Motivation to Combine

All of the claims on appeal are directed to a hemodialysis machine integrated with a touch screen user interface, which Baxter contends was novel and nonobvious at the time the relevant patent applications were filed. Fresenius contends that touch screens were well-known in the prior art and had been widely employed—even on other medical devices—such that Baxter's addition of a touch screen interface to an otherwise conventional hemodialysis machine would have been obvious and thus unpatentable.

The district court conducted the trial and issued its JMOL opinion before the Supreme Court decided KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007). Thus, the district court applied the teaching-suggestion-motivation test for obviousness as it existed before it was modified by KSR. The district court granted JMOL and overturned the jury's verdict that all asserted claims of the '131 and '434 patents are invalid as obvious because it determined that Fresenius had failed to demonstrate the required motivation to combine.

We first note that it remains appropriate for a post-KSR court considering obviousness "to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." KSR, 550 U.S. at 418. Thus, the jury's obviousness verdict remains relevant to our review because we will not overturn the implicit factual findings underlying the jury's verdict so long as they are supported by substantial evidence. See LNP Eng'g Plastics, 275 F.3d at 1353. As explained below,

Fresenius presented substantial evidence to support the jury's implicit factual finding that the prior art suggested the combination of a touch screen user interface with known elements of prior art hemodialysis machines.[3] Thus, we reverse the district court's grant of JMOL as to the asserted claims in the '131 patent.

Baxter concedes that Fresenius presented a prior art publication that disclosed the use of a touch screen interface on a medical device—specifically an anesthesia-delivery system. That publication noted hemodialysis as one rapidly advancing area of medicine, stated that complex technologies have fueled such rapid advances, and then disclosed that the equipment necessary to practice those complex technologies could benefit from an improved user interface. J.A. at 18048. The publication then specifically described the integration of a touch screen interface with an anesthesia-delivery system. Dr. Rau, the author of the publication, explained to the jury where his publication mentioned hemodialysis and pointed to other sections of the publication that, in his opinion, suggested the addition of a touch screen to a hemodialysis machine. J.A. at 14373–75. Specifically, Dr. Rau testified that his publication "gave numerous examples of where you can use [touch screen technology] beneficially" and stated that "one of the examples which I mentioned was hemodialysis and a hemodialysis machine." J.A. at 14373–75. Dr. Phares, another Fresenius witness, described the

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[3] The jury was instructed that "[t]he claimed invention is not obvious unless there was something in the prior art or within the understanding of a person of ordinary skill in the field that would suggest the claimed invention." Jury Instructions at 26.

ease and prevalence of "integrating a touch screen into some kind of a computer-controlled machine" and opined that as of the relevant filing date, it would not have been difficult for one to integrate a touch screen interface into a hemodialysis machine. J.A. at 14321–22.

Under KSR, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." 550 U.S. at 417. In addition, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Id. at 416. Here, the jury implicitly found that the prior art suggested combining a touch screen with known elements of a hemodialysis machine. That finding is supported by substantial evidence because a reasonable jury could conclude that Dr. Rau's publication contained an explicit suggestion to combine the disclosed benefits of a touch screen interface with a hemodialysis machine. In addition, the jury could reasonably conclude, based on Dr. Phares's testimony, that an ordinarily skilled artisan would have known how to make that combination. Thus, substantial evidence supports the jury's findings that the limitations of the '131 patent claims were known in the prior art, that the prior art suggested combining those elements to arrive at the claimed invention, and that the ordinarily skilled artisan would have known how to make that combination. Therefore, JMOL is inappropriate under KSR, and we reverse the district court's grant of JMOL regarding all asserted claims of the '131 patent. However, as discussed above, Fre-

senius failed to present evidence that all limitations present in claims 26–31 of the '434 patent were present in the prior art—thus, we affirm the district court's grant of JMOL as to those claims.

Baxter argues it presented objective evidence sufficient to demonstrate that its invention was not obvious. However, it was the proper role of the jury to assess the credibility and weight of Baxter's evidence regarding the difficulties of integrating a hemodialysis machine with a touch screen interface and the commercial success of an embodiment of the patents. The jury was instructed that it must consider that evidence. Jury Instructions at 26–27. Therefore, to render its verdict on obviousness, the jury necessarily determined that Baxter's evidence was insufficient to overcome Fresenius's showing that the claims are invalid as obvious. We will not disturb that implicit factual finding because it is supported by substantial evidence.

IV. The Permanent Injunction and Royalty Award

Fresenius argues that the district court abused its discretion when it permanently enjoined Fresenius and awarded Baxter a royalty on hemodialysis machines sold before January 1, 2009, and disposables linked to those machines. Although we hold that the district court did not err when it determined that injunctive relief is appropriate, we vacate the injunction and remand for the district court to revise or reconsider the injunction in light of our reversal of JMOL. We likewise vacate the royalty award and remand for the district court to reconsider that award in view of this opinion.

A. The Permanent Injunction

To obtain a permanent injunction, the prevailing patentee must demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, 547 U.S. at 391.

The district court performed the appropriate analysis required by eBay. It weighed all of the factors and explained why it ultimately determined that injunctive relief is appropriate. Injunction Order, slip op. at 3–8. Contrary to Fresenius's assertion, the district court did not consider the permanent injunction to be "all but inevitable" following the infringement determination.[4] Fresenius asserts several additional

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[4] The district court did discuss an injunction as "all but inevitable," but it did so in the context of balancing the relative hardships to the parties and did not commit legal error. The district court noted that it was "somewhat bewildering that, having admitted to infringing the patents nearly two years ago and having known for at least a year that an injunction was all but inevitable, Fresenius has apparently done nothing to implement any alternative to the [accused infringing device]." Injunction Order, slip op. at 7 (emphasis added). The district court then found that the balance of hardships favored Baxter because "[i]t is Fresenius's burden, and not Baxter's, to taste

challenges to the district court's analysis, but it cites no legal error and fails to demonstrate that the district court made any clearly erroneous factual determinations. For example, Fresenius asserts that the district court "ignored" evidence, see Appellant's Br. at 50–52, but there is no requirement that the district court's opinion discuss every single fact alleged by Fresenius. In addition, the record contains support for the district court's factual determinations; the district court did not clearly err. Thus, we conclude that the district court did not abuse its discretion when it granted permanent injunctive relief. Nonetheless, we vacate the injunction and remand for the district court to revise or reconsider the injunction in light of our reversal of the district court's grant of JMOL regarding the '027 and '131 patents.

B. The Royalty Award

The district court ordered Fresenius to pay an ongoing royalty of 10% of the sales price for any infringing machines sold before January 1, 2009, and a royalty of 7% of the sales price for all disposable products linked to infringing machines that were sold from November 7, 2002, until the patents expire. Injunction Order, slip op. at 9–10. Fresenius argues the district court abused its discretion by imposing

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the bitter fruit of its own inaction." Id. Read in context, the "all but inevitable" statement does not amount to legal error, particularly in light of the fact that the district court applied the correct four-factor test and explained its analysis. The district court was likely merely acknowledging, as did Chief Justice Roberts in eBay, that "courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases." eBay, 547 U.S. at 395 (Roberts, C.J., concurring).

the ongoing royalty without explaining the bases for its royalty rate determinations. See Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007) (remanding because, absent an explanation of the selection of the royalty rate, this court cannot determine whether the district court abused its discretion) (citing Hensley v. Eckerhart, 461 U.S. 424, 437 (1983) ("It [is] important . . . for the district court to provide a concise but clear explanation of its reasons for the fee award.")).

We do not decide today whether the district court's royalty award was proper. Instead, we vacate the royalty award and remand for the district court to consider whether the previous award is proper in light of this court's modification of the district court's judgment. In particular, we note that our reversal of JMOL may affect the district court's consideration of the putative royalty rate that would result from a hypothetical negotiation between Baxter and Fresenius. That analysis is influenced by the Georgia Pacific factors, see Minks v. Polaris Indus., 546 F.3d 1364, 1372 (Fed. Cir. 2008), and our decision here may affect how the district court weighs one of more of those factors, see Georgia-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

Fresenius also argues that the district court erred by imposing a royalty on post-verdict sales of disposables linked to machines that were sold pre-verdict. According to Fresenius, that portion of the royalty is inappropriate because the jury had already awarded Baxter damages based on machines sold pre-verdict. We disagree because the district court acted within its discretion. A damages award for pre-verdict sales of the infringing product does not fully compensate the patentee because it fails to account

for post-verdict sales of repair parts. See Carborundum Co. v. Molten Metal Equip. Innovations, Inc., 72 F.3d 872, 881–82 (Fed. Cir. 1995). Although the jury had awarded damages for Fresenius's pre-verdict sales of machines and disposable products, Fresenius cites no evidence indicating that the jury also considered post-verdict sales of disposable products linked to machines sold pre-verdict. The district court was within its discretion to impose a royalty on those sales of disposable products in order to fully compensate Baxter for the infringement.

V. Other Arguments

We have considered the parties' other arguments and find them unpersuasive. For example, Fresenius asserts that the district court erred in construing two claim terms: the "means for controlling a dialysate parameter" term in claim 26 of the '434 patent and the "time variable profile" term in all asserted claims of the '131 patent. We decline to consider those arguments. First, Fresenius failed to clearly explain what result would occur if this court adopted Fresenius's proposed claim constructions. Fresenius gave this court little guidance and cited no record support regarding why a modified claim construction would affect the infringement judgment, the validity judgment, or both. For that reason alone, we may decline to consider Fresenius's claim construction arguments. See Jang v. Boston Sci. Corp., 532 F.3d 1330, 1336 (Fed. Cir. 2008) ("The Supreme Court has explicitly held that Article III does not permit the courts to resolve issues when it is not clear that the resolution of the question will resolve a

concrete controversy between interested parties." (citing Coffman v. Breeze, 323 U.S. 316, 322–24 (1945))). In addition, to the extent Fresenius contends a modified claim construction may affect the infringement judgment, we disagree. Fresenius unconditionally stipulated that its accused infringing device contains each and every element of the claims, J.A. at 13721, and then proceeded to argue invalidity at trial. That stipulation in no way stated or indicated that it was conditioned upon the district court's claim construction, and thus, the infringement judgment cannot be altered by a modified claim construction. Finally, to the extent Fresenius's proffered claim constructions would support its invalidity arguments, we note that we have not relied on the contested claim terms for any holdings adverse to Fresenius, and thus, the claim construction arguments are moot as to the issue of validity.

Baxter asserts that it is entitled to a new trial if this court determines that the district court's grant of JMOL was erroneous. We disagree. We have decided the invalidity issues as a matter of law, and no new trial is warranted.

VI. CONCLUSION

Because Fresenius failed to demonstrate that the structures corresponding to certain means-plus-function claim limitations were present in the prior art, we affirm the district court's judgment that Fresenius failed to prove that claims 26–31 of the '434 patent are invalid. We reverse the district court's grant of JMOL as to all other asserted claims. In addition, although we hold that the district court did

not abuse its discretion when it permanently enjoined Fresenius, we vacate the injunction and remand so that the court may revise or reconsider the injunction in light of the fact that only claims 26–31 of the '434 patent remain valid and infringed. Finally, we vacate the royalty award entered by the district court and remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC. and
FRESENIUS MEDICAL CARE HOLDINGS, INC.,
Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,

Defendants-Cross Appellants.

Appeals from the United States District Court for the Northern District of California in Case no. 03-CV-1431, Judge Saundra Brown Armstrong.

NEWMAN, Circuit Judge, concurring.

I join the court's opinion, but I write separately to respond to Judge Dyk's separate opinion, in which he proposes that the district court should stay completion of this litigation, in view of the pending reexamination proceeding. Although this proposal is not adopted it warrants response, for at this stage in this protracted litigation, after full trial and decision in the district court, after full appeal and ruling of the appellate court and with only a modified remedy remaining on remand, such an action would be inappropriate. Further, this question has been neither briefed nor debated. Its sua sponte presentment as available at this stage is irregular.

This litigation began in 2003. Only an issue of adjustment of damages and a modification of the permanent injunction to reflect our reversal of JMOL remain on remand. Meanwhile, the reexamination has yet to be finally decided at the PTO, and remains subject to judicial review, on the same issues of validity as have been litigated. The proposal would entail several years' additional delay, if the court were now to stay the action at this final stage.[1]

The relationship between reexamination and litigation is not new to the courts, and precedent reflects the variety of responses in particular situations, as summarized in Slip Track Systems, Inc. v. Metal Lite, Inc., 159 F.3d 1337, 1341 (Fed. Cir. 1998) with respect to concurrent proceedings including PTO reexamination and PTO interference proceed-

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[1] Our colleague in concurrence appears to believe that a PTO decision on reexamination will override a judicial decision reached after trial and appeal. That is incorrect. All that can be accomplished is delay. In exercising its discretion to deny or grant a stay pending reexamination, a district court should consider the effect of delay upon a patentee. With respect to inter partes reexamination, 35 U.S.C. §318 commits the grant of a stay to the district court's discretion with special heed to the concerns of the patentee:

> Once an order for inter partes reexamination of a patent has been issued under section 313, the patent owner may obtain a stay of any pending litigation which involves an issue of patentability of any claims of the patent which are the subject of the inter partes reexamination order, unless the court before which such litigation is pending determines that a stay would not serve the interests of justice.

(emphasis added).

ings. It is established that a "court is not required to stay judicial resolution in view of the reexaminations." Viskase Corp. v. American Nat'l Can Co., 261 F.3d 1316,1328 (Fed. Cir. 2001). The corollary rule is that the PTO has no authority to stay reexamination pending the outcome of district court litigation. Ethicon, Inc. v. Quigg, 849 F.2d 1422 (Fed. Cir. 1988). A stay of finality, after the issues of validity and infringement have been litigated and decided by the district court and appealed to the Federal Circuit, is a distortion of the role of reexamination.

I remain a strong supporter of the principle of reexamination. It can be a useful and powerful tool for the benefit of both patentees and those interested in restricting or eliminating adversely held patents. However, if routinely available to delay the judicial resolution of disputes, the procedure is subject to inequity, if not manipulation and abuse, through the delays that are inherent in PTO activity. The statistical data of the Patent and Trademark Office place this aspect in sharp relief, for the number of reexamination requests is increasing, as is the time for completion of reexamination and appeal in the PTO, as well as the right of judicial review. In its recent statistical summaries, the PTO reports a 54% increase in filing of ex parte reexaminations since 2004 (from 441 in 2004 to 680 in 2008, and with 481 filings through June 2009). See USPTO, Reexamination Operational Statistics (June 30, 2009), available at http://www.uspto.gov/web/patents/documents/reexam_operations_06-09.pdf. Of these filings 31% were reported to be in litigation. Id. Inter partes reexaminations are increasing rapidly, from 168 in 2008 to 195 filings through June of 2009, with 66% reported to be

in litigation. Id. The PTO also reports that as of the third quarter of 2009, the average pendency for ex parte reexamination is 36.1 months, an increase from the 34.6 months at December 2008. Id. The pendency of inter partes reexamination is reported to average 41.7 months. Id.

Decisions on reexamination can be appealed to the Board and are subject to judicial review. The PTO reports that the Board is still experiencing a heavy increase in appeals and the backlog of appeals. In contrast, the present case is over but for review of the remedy on remand. The suggestion that the district court should now stay the proceedings, at this final stage, is contrary to the precepts of expeditious and just resolution of disputes.

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC. and
FRESENIUS MEDICAL CARE HOLDINGS, INC.,
Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,
Defendants-Cross Appellants.

Appeals from the United States District Court for the Northern District of California in case no. 03-CV-1431, Judge Saundra Brown Armstrong.

DYK, Circuit Judge, concurring.

I join the majority opinion on the understanding that it does not foreclose the district court in its discretion from staying further proceedings pending the outcome of the reexamination before the U.S. Patent and Trademark Office. While Fresenius did not establish the invalidity of claims 26–31 of the '434 patent in the district court proceeding, those claims on their face are of dubious validity in light of our holding that claims 1–3 and 13–16 of the '131 patent and claim 11 of the '027 patent are invalid. It is entirely possible that the U.S. Patent and Trademark Office will finally conclude that claims 26–31 of the '434 patent are also invalid.

APPENDIX B

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC. and
FRESENIUS MEDICAL CARE HOLDINGS, INC.,

Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,

Defendants-Cross Appellants.

Appeals from: United States District Court for the Northern District of California in case no. 03-cv-1431, Judge Sandra Brown Armstrong.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A petition for rehearing en banc having been filed by the Appellants, and a response thereto having been invited by the court and filed by the Cross-Appellants, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having referred to the circuit judges who are in regular active service.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and same hereby is, DENIED.

The mandate of the court will issue on November 25, 2009.

FOR THE COURT,

Jan Horbaly

Dated: 11/18/2009

APPENDIX C

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

FRESENIUS MEDICAL CARE HOLDINGS, INC., *et al.*,
Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., *et al.*,
Defendants.

No. C 03-1431 SBA

ORDER

[Docket Nos. 845, 847]

This matter comes before the Court on defendants Baxter International, Inc. and Baxter Healthcare Corporation's (Baxter) Rule 50(b) Renewed Motion for Judgment as a Matter of Law [Docket No. 847], and Baxter's Motion for a New Trial Pursuant to Rule 59 [Docket No. 845]. Baxter seeks judgment as a matter of law (JMOL) that all of the asserted claims of U.S. Patent No. 5,247,434 (the '434 Patent), U.S. Patent No. 6,284,131 (the '131 Patent), U.S. Patent No. 5,326,476 (the '476 Patent), and U.S. Patent No. 5,744,027 (the '027 Patent) are not invalid. After reading and considering the arguments presented by the parties, the Court finds this matter appropriate for resolution without a hearing. For the reasons that follow, the Court GRANTS Baxter's renewed JMOL [Docket No. 847] and GRANTS Baxter's motion for a new trial [Docket No. 845].

PROCEDURAL HISTORY

On April 4, 2003, plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (Fresenius) filed a complaint seeking declaratory judgment of invalidity and non-infringement of five patents held by Baxter. One of the patents, U.S. Patent No. 5,486,286, is no longer at issue. Baxter commercialized the inventions of the patents through hemodialysis instruments, such as the Drake Willcock™ System 1000 Dialysate Delivery System (System 1000). A hemodialysis machine is a kidney dialysis machine that removes metabolic waste from a patient's blood by circulating the blood through an extracorporeal circuit. *See* Docket 835-1 (Jury Instr. at 19). On May 14, 2003, Baxter answered and counterclaimed that Fresenius's 2008H and/or 2008K hemodialysis machines infringe four of the five patents. Fresenius responded by identifying the Sarns 9000 as prior art that invalidated the patents held by Baxter.

On September 2, 2005, the Court granted in part Baxter's motion for partial summary judgment and granted in part Fresenius's cross-motion for summary judgment, and held that Fresenius's 2008K hemodialysis infringed claim 26 of the '434 patent and claim 1 of the '131 patent. *See* Docket No. 370. The Court also held that the SVS, Kt/V, and Blood Pressure screens of the 2008K did not infringe claim 1 of the '131 patent.

On March 10, 2006, pursuant to a stipulation between the parties, the Court issued an order dismissing with prejudice: (1) all claims, counterclaims, and defenses of the parties concerning the '286 pat-

ent and claims 1 and 6 of the '476 patent; (2) all claims, counterclaims, and defenses of the parties concerning Fresenius's 2008H hemodialysis machine; (3) Fresenius's affirmative defenses of laches, estoppel, failure to mark, and prosecution laches with respect to all the patents-in-suit; (4) Fresenius's affirmative defense of unenforceability with respect to the '286 patent and the '027 patent; (5) Fresenius's defense of improper inventorship based on the alleged contribution by Ziba Design with respect to all of the patents-in-suits; and (6) Fresenius's defense of indefiniteness as to claims 1, 13, and 14 of the '131 patent. *See* Docket No. 484.

On May 16, 2006, the Court found that the '434 patent was not anticipated by the Sarns 9000. *See* Docket No. 661. On June 15, 2006, Fresenius stipulated that its 2008K hemodialysis machine meets every claim limitation of the '434, '131, and '027 patents. *See* Docket No. 755. The Court then entered a judgment of partial infringement reflecting this stipulation. *See* Docket No. 770.

The remaining dispute for the jury to resolve was whether Fresenius's 2008K hemodialysis machine infringed upon claims 26 through 31 of the '434 patent, claims 1, 2, 3, 13, 14, 15, and 16 of the '131 patent, claims 7, 11, 14, 15, and 16 of the '027 patent, and claims 5 and 7 of the '476 patent. Fresenius asserted that the claims of these patents were invalid either because they were obvious in light of prior art or because they were anticipated by prior art.

The jury returned a unanimous verdict on June 30, 2006, finding in favor of Fresenius on all issues submitted to it. *See* Docket No. 829. The jury found that all remaining claims were either invalid as obvious and/or invalid as anticipated, and that the

Fresenius 2008K did not infringe on either claim 5 or 7 of the '476 patent. Specifically, the jury found that Fresenius proved by clear and convincing evidence that claims 26, 27, 28, 29, 30, and 31 of the '434 patent were invalid as obvious based on prior art; that Fresenius proved by clear and convincing evidence that claims 1, 2, 3, 13, 14, 15, and 16 of the '131 patent were invalid as obvious based on prior art; that Fresenius proved by clear and convincing evidence that claims 5 and 7 of the '476 patent were invalid as obvious based on prior art; and that Fresenius proved by clear and convincing evidence that claims 7, 11, 14, 15, and 16 of the '027 patent were invalid as obvious based on prior art. With respect to the '027 patent, the jury also held that Fresenius proved by clear and convincing evidence that claims 7, 14, 15, and 16 were invalid as anticipated based on prior art. The jury next determined that Baxter failed to prove by a preponderance of the evidence that the Fresenius 2008K hemodialysis machine literally infringes on claim 5 or 7 of the '476 patent. *See* Docket No. 829 (Jury Verdict Form).

LEGAL STANDARDS

Federal Rule of Civil Procedure 50(a) governs judgments as a matter of law. This rule provides that "If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may . . . grant a motion for judgment as a matter of law." FED. R. CIV. P. 50(a)(1). A party may renew its request for judgment as a matter of law by filing a mo-

tion no later than 10 days after entry of judgment. *See* FED. R. CIV. P. 50(b). A party may alternatively request a new trial under Rule 59. *See id.*

The party requesting the JMOL must show that substantial evidence does not support the jury's findings. *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1149 (Fed. Cir. 2004). "Substantial evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1362 (Fed. Cir. 2001) (citation omitted). The Court considers all evidence before the jury and draws all reasonable inferences from the evidence in the light most favorable to the prevailing party on that issue. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (en banc); *Koito Mfg.*, 381 F.3d at 1149. A jury verdict on obviousness, however, is reviewed without deference because obviousness is a question of law. *See Koito Mfg.*, 381 F.3d at 1149.

Because a patent is presumed valid, the quantum of proof required at trial for a finding of invalidity is clear and convincing evidence. 35 U.S.C. § 282 ("A patent shall be presumed valid"); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 736 (Fed. Cir. 2002). This burden "shall rest on the party asserting such invalidity." 35 U.S.C. § 282. The validity of each claim of a patent is evaluated independently of the others and the party challenging the validity of a claim must submit evidence supporting a conclusion of invalidity of each claim the challenger seeks to destroy. *Id.*; *see also Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992).

Under 35 U.S.C. § 103, patent claims are rendered invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The "party seeking a judgment that a patent is obvious bears the burden of demonstrating by clear and convincing evidence that the teachings of the prior art would have suggested the claimed subject matter to one of ordinary skill in the art." *Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1187 (Fed. Cir. 2002). "Invalidity based on obviousness is a question of law based on the underlying facts. The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998) (citations omitted). Knowledge in the prior art of every element of a patent claim by itself is not sufficient to render a claim obvious. *Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1357 (Fed. Cir. 2003); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987).

Invalidity due to obviousness may result from a combination of prior art references. When prior art references are combined to invalidate a claim under 35 U.S.C. § 103, the prior art must provide some teaching, suggestion, or motivation to combine the references. *Akamai Techs., Inc. v. Cable Wireless*

Internet Serv., Inc., 344 F.3d 1186, 1196 (Fed. Cir. 2003); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). A party may not use hindsight analysis to show that, in light of the patented invention, it would have been obvious to combine prior art references. *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). The teaching, suggestion, or motivation to combine references may come from the teachings of the references themselves, from the knowledge generally available to one of ordinary skill in the art, or may "flow from the nature of the problem." *Akamai*, 344 F.3d at 1196 (citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2002). A showing, teaching, or motivation to combine prior art references must be clear and particular, and must be supported by actual evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002). Broad, conclusory statements about the teaching of prior art are insufficient. *Brown & Williamson*, 229 F.3d at 1125. Moreover, a prior art reference that merely offers an "invitation to try" for improvements in the relevant art, without suggesting a means to accomplish such improvement, is insufficient to prove obviousness. *See In re O'Farrell*, 853 F.2d 894, 903 (Fed Cir. 1988) (discussing "obvious to try" cases); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986).

ANALYSIS

A. Motion for Judgment as a Matter of Law

Baxter proffers seven arguments in its motion for judgment as a matter of law. Baxter maintains that:

1. Fresenius failed to offer any combination of prior art teaching of all of the claim limitations for claim 14 of the '131 patent;
2. Fresenius failed to offer any combination of prior art teaching of all of the claim limitations for claims 28, 29, and 30 of the '434 patent;
3. Fresenius failed to offer any evidence on element (a) of claim 26 of the '434 patent and element (a) of claim 1 of the '131 patent;
4. Fresenius failed to offer clear and convincing evidence of a motivation to combine the '131 and '434 patents;
5. Fresenius failed to identify evidence of obviousness and failed to identify a motivation to combine claim 7 of the '476 patent;
6. Fresenius missed claim elements and offered no evidence of a motivation to combine for claim 5 of the '476 patent; and
7. Fresenius failed to address the entirety of dependent claim 11 of the '027 patent

> and failed to provide a motivation to combine.[1]

As an initial matter, Fresenius contends the first two contentions are precluded because Baxter failed to raise them in its original JMOL, as it never specifically mentioned dependent claims 28, 29, and 30 of the '434 patent or claim14 of the '131 patent. A party cannot raise arguments in its post-trial JMOL under Rule 50(b) that it did not raise in its pre-verdict Rule 50(a) motion. *Freund v. Nycomed Amersham*, 347 F.3d 752, 761 (9th Cir. 2003).

In Baxter's Rule 50(a) Motion for Judgment as a Matter of Law, it did not specifically break out claim 14 of the '131 patent or claims 28, 29, and 30 of the '434 patent from its general contention that "For the Claims of the '131 and '434 Patents, Fresenius Has Failed to Offer Clear and Convincing Evidence of Motivation to Combine." *See* Docket No. 808. In its motion Baxter stated:

> For the '131 and '434 patents, Fresenius offered Dr. Rau and Mr. Causey. Dr. Rau never offered the opinion that any *claim* of the '131 or '434 patents was obvious. Rather, he testified that *element (b)* of 131:1 and *element (b)* of 434:26 were obvious.
>
> . . . .
>
> Mr. Causey's testimony fails to provide the type of clear and convincing evidence required to invalidate Baxter's patent claims as

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[1] Baxter does not challenge the jury's verdict that claims 7, 14, 15, and 16 of the '027 patent are invalid as anticipated by prior art. *See* Docket No. 829 (Jury Verdict at 3).

> obvious, and the Court may grant JMOL to Baxter.

Docket 808 at 10, 14 (emphasis in original).

The language recited above is broad enough to encompass claim 14 of the '131 patent and claims 28, 29, and 30 of the '434 patent. The issue is whether it was specific enough to give Fresenius notice that Baxter was challenging the sufficiency of evidence with respect to those particular claims. *See Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1105-06 (Fed. Cir. 2003).

Although JMOL issues are generally governed by regional circuit law, Federal Circuit law governs whether arguments made in pre-verdict JMOLs are sufficient enough to preserve specific patent law issues for a post-verdict JMOL. *See Junker v. Eddings*, 396 F.3d 1359, 1363 (Fed. Cir. 2005); *Duro-Last*, 321 F.3d at 1106. Rule 50(a) provides that a motion for JMOL made before the case is submitted to the jury "shall specify . . . the law and the facts that entitle the movant to the judgment." FED. R. CIV. P. 50(a)(2). Like other circuits, the Federal Circuit requires that a Rule 50(a) motion be sufficiently specific regarding its factual basis to inform the opposing party of exactly what is alleged to be deficient in its evidence, thereby giving the opposing party an opportunity to cure the defects in proof. *See Junker*, 396 F.3d at 1363. The district court is in the best position to judge the sufficiency of the Rule 50(a) motion in the context of the trial. *See Gaus v. Conair Corp.*, 363 F.3d 1284, 1287 (Fed. Cir. 2004).

In *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1107 (Fed. Cir. 2003), the Federal Circuit

noted, for instance, that a pre-verdict JMOL on the issue of anticipation would not be sufficient to support a post-verdict JMOL on obviousness because they are legally distinct and separate challenges to a patent's validity. And in *Junker v. Eddings*, 396 F.3d 1359, 1363 (Fed. Cir. 2005), the Federal Circuit found that a post-verdict JMOL raising specific elements of the patent in question were not supported by the pre-trial JMOL that referred only in general terms to the "design claimed in the patent."

Three other cases reached the opposite result. In *Gaus v. Conair Corp.*, 363 F.3d 1284, 1287 (Fed. Cir. 2004), the Federal Circuit upheld a district court's decision that a party did not waive its noninfringement claim in its post-verdict motion for JMOL where it raised the same arguments earlier, although in an abbreviated and terse form. In *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566 n.6 (Fed. Cir. 1996), and in *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1324-25 (Fed. Cir. 1991), the court held that very brief, oral pre-verdict motions for JMOL were sufficient to support a renewed JMOL. From these authorities, it appears the Federal Circuit follows most circuits in liberally allowing renewed JMOLs,[2] as long as they do not raise issues entirely distinct and separate from the original JMOL.

In this case, there is no dispute that Baxter raised the issue of obviousness in its original Rule 50

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[2] *See* 9A C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2537 (3d ed. 1998); *see also Farley Transp. Co. v. Santa Fe Trail Transp. Co.*, 1342, 1347 (9th Cir. 1985).

motion. It also challenged the sufficiency of evidence with regard to obviousness specifically concerning patents '131 and '434. Obviousness was a major issue at the trial. Thus, the Court finds this situation more analogous to *Gaus*, *Texas Instruments*, and *Malta* rather than *Duro-Last* and *Junker*. Accordingly, the Court will review the merits of Baxter's arguments concerning claim 14 of the '131 patent and claims 28, 29, and 30 of the '434 patent.

1. Claim 14 of the '131 Patent

Claim 14 of the 131 patent requires that the touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." Docket 835-1 (Jury Instr. at 15). Baxter contends that Fresenius has failed to establish the invalidity of claim 14 because it relied only on the combination of the Cobe Manual and the Sarns 9000 to meet the claim elements. This Court has found that the Sarns 9000 Manual does not disclose the display of any indicium corresponding to time-variable hemodialysis parameters. As the Court has previously noted, the Sarns 9000 is a heart-lung machine and not a hemodialysis apparatus, and the Sarns 9000 "does not meet the 'time-variable profile' claim limitation." Docket No. 661, at 25-28. And Baxter points out that the Cobe Manual shows only one indicium relating to a time-variable hemodialysis parameter—programmable sodium. *See* PTX 240, Cobe Manual at F0145546.

For its part, Fresenius notes that its witness, James Causey, testified that claim 14 is obvious in view of prior art. Tr. at 835:13-836:21. Causey testified that "the engineers that developed the Cobe Ma-

chine have provided opportunities to add more time-variable parameter within this –." Tr. at 836:8-10. It adds that the Cobe C3 Manual discloses an indicium corresponding to a time-variable hemodialysis parameter and that the Sarns 9000 has a touch screen. From this the jury could have reasonably concluded that it would have been obvious to add indicia corresponding to other time variable parameters. It also notes the testimony of Charles Ragsdale that the Seratron Modeling Programmer Manual allows for UF profiling and sodium profiling and that the Modeling Programmer has several buttons corresponding to different time-variable hemodialysis parameters. Fresenius also relies on the testimony of Robert Pares that touch screens have been integrated into computer-controlled machines hundreds of times.

Fresenius did not show any of the cited pages of the Seratron Modeling Programmer Manual to the jury nor offered any expert testimony explaining the buttons on the modeling programmer to it. Moreover, the Seratron Modeling Programmer does not have a touch screen or any CRT display and therefore this reference fails to teach the missing claim elements because it does not "display" any indicia. Accordingly, Fresenius has not identified any prior art that would "display a plurality of indicia each corresponding to a different time variable hemodialysis parameter," and thereby provide substantial evidence supporting the jury verdict. The Cobe C3 Manual discloses a single indicium. The Sarns 9000 Manual discloses none. The Seratron Modeling Programmer does not have a touch screen or any CRT display. *See* PTX 1213C; *see also* PTX 380. The Federal Circuit has held that where no combination of prior art references describes the particular functions recited in

a claim, a jury's verdict on obviousness must fall. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997). With respect to Causey's testimony that "the engineers that developed the Cobe Machine have provided opportunities to add more time-variable parameter within this –", such confusing or generalized testimony as evidence of invalidity is improper. *See Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002). Therefore, there is not substantial evidence to support the jury's finding on claim 14 of the '131 patent.

2. Claims 28, 29, and 30 of the '434 Patent

Claim 28 of the '434 patent requires "means for delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient, wherein the touch screen further provides a visual display of a parameter associated with said means for delivering blood." Docket No. 835-1 (Jury Instr. at 14). Claim 29 provides that "the parameter associated with said means for delivering blood is selected from a group consisting of blood flow rate, arterial blood pressure, and venous blood pressure." Docket No. 835-1 (Jury Instr. at 14). Claim 29 is dependent on claim 28. Claim 30 requires "means for delivering an anticoagulant to a patient, wherein the touch screen further provides an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery." Docket No. 835-1 (Jury Instr. at 14). For claim 30, the Court instructed the jury that the structure corresponding to the "means for delivering an anticoagulant" is a microprocessor and a stepper motor. *See* Docket 835-1 (Jury Instr. at 21).

Baxter argues that Fresenius's witness Causey failed to discuss the means-plus-function claim elements or the structures required by them and that his testimony was therefore insufficient to prove obviousness. *See* Tr. at 824:2-827:24. Baxter also maintains that the single page of the Cobe Manual relied upon by Causey lacks any mention of a structure meeting either party's construction for "means for delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient" and that Causey offered no testimony regarding this claim limitation.

Causey testified that claim 28 is obvious in light of prior art—the Cobe C3 Manual (which displays venous and arterial pressure) and the Sarns 9000 (which has a touch screen). Tr. at 824:2-825:6. Baxter contends that none of the pages of the Cobe C3 Manual cited by Fresenius in its response were shown to the jurors or discussed in front of them by any of the eleven witnesses called by Fresenius. Fresenius does not rebut or effectively dispute this. Moreover, Fresenius does not identify any evidence given to the jury describing a microprocessor or a microprocessor with a blood pump performing the claimed function, *i.e.*, "delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient." Title 35 U.S.C. § 103 requires that the entire claim, or the "subject matter as a whole" be analyzed. Because not all of claim 28 was analyzed, evidence of invalidity is lacking.

Causey also testified that claim 29 is invalid in view of prior art. Tr. at 825:7-826:13. Baxter contends that claim 29 is dependent on and includes all of the limitations of claim 28. Thus, a failure of proof

on claim 28 would extend to claim 29 as well. Fresenius simply counters that there is sufficient evidentiary support for claim 28, and therefore claim 29 is also met. As the Court has found otherwise, sufficient evidence is also lacking to support the jury's finding on claim 29, and it too must be set aside.

Causey testified that claim 30 is invalid in view of prior art, namely the Cobe C3 Manual, which shows that the Cobe machine allows the controlled delivery of the anticoagulant heparin. Tr. at 826:14-827:24. However, the jury was instructed that "means for delivering an anticoagulant" is a microprocessor and a stepper motor. In its response to Baxter's motion, Fresenius makes no argument and indeed identifies no prior art that meets this construction. Fresenius response is that other machines delivered anticoagulants. This is insufficient evidence to support the jury's finding with respect to claim 30 because the prior art relied upon by Fresenius did not contain an equivalent structure to the disclosed structure for the means-plus-function claim term. *See Kahn v. General Motors Corp.*, 135 F.3d 1472, 1480 (Fed. Cir. 1998). Accordingly, the jury's findings on claims, 28, 29, and 30 must fall.

3. Element (a) of Claim 26 of the '434 Patent and Element (a) of Claim 1 of the '131 Patent

Element (a) of claim 26 requires "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer." Docket No. 835-1 (Jury Instr. at 14). The jury

was instructed that the function associated with the "means for controlling a dialysate parameter" is "controlling dialysate temperature and/or controlling dialysate concentration," and that the structure for controlling dialysate temperature is a "microprocessor, a heater, and a temperature sensing device;" the structure for controlling dialysate concentration is a "microprocessor and a concentrate pump." Docket No. 835-1 (Jury Instr. at 21). Element (a) of claim 1 of the '131 patent provides "a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit." Docket No. 835-1 (Jury Instr. at 15).

Baxter maintains that neither expert offered by Fresenius to prove the invalidity of the '131 and '434 patents—Dr. Gunter Rau or Causey—sufficiently addressed element (a) of claim 26 or element (a) of claim 1 because Dr. Rau only testified that element (b) of each claim was obvious, not element (a), and because Causey improperly "boiled down" element (a) in contravention of Federal Circuit law.

Fresenius offers little argument that Dr. Rau offered testimony on element (a) of either claim, only that his testimony in combination with all of the other evidence supports the verdict. A review of the record does show that Dr. Rau's testimony is limited to an analysis of element (b) of claim 1 and element (b) of claim 26. *See* Tr. 594:6-11; 599:20-600:10; 601:6-21.

Causey testified that claim 26 is obvious, pointing to the Cobe C3 Manual, the CMS 08 Manual, in combination with the Sarns 9000. Tr. at 821:6-822:17. The Cobe C3 Manual, however, does not appear to disclose the required structure for element (a) of claim 26. The pages cited by Fresenius do not mention a microprocessor and a heater and/or a temperature sensing device, or a microprocessor and a concentrate pump. *See* Docket No. 849, Ex. 5 (Abernathy Decl.). Nor does the CMS 08 Manual appear to provide disclosure of the required structure. The cited pages do not disclose a microprocessor, a heater, or a temperature sensing devices or the required "means for delivering the dialysate to a dialysate compartment of a hemodialyzer."

Fresenius further maintains that the limitations of element (a) of claim 26 are met by the Seratron System. Dr. Ben J. Lipps testified that the Seratron marketing literature describes the requirements of element (a) at a high level [Tr. at 222:5-19, 224:7-225:5] and that the Seratron Technician's Manual describes the inner workings of the machine. But this evidence is flawed. While the Seratron Technician's Manual was admitted into evidence, the only witness testimony concerning it was offered by Ragsdale who discussed one page of the Manual in reference to the '027 patent. Tr. at 549:10-552:2. There was no witness testimony connecting it to the '434 patent. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1325 (Fed. Cir. 2005) (expert's direct testimony was conclusory and failed to analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim); *Koito*, 381 F.3d at 1152-54. Conclusory evidence is insufficient to meet Fresenius's bur-

den of clear and convincing evidence. Nor is it convincing that the page mentioned (PTX 383 at F006581) discloses the required structure of element (a).

Turning next to claim 1 of the '131 patent, Causey testified that it is obvious based on the CMS 08/A2008 system or the CMS 08 Manual, in combination with the Sarns 9000. Tr. at 829:16-830:12. His testimony on this point was rather brief; he testified simply that it claimed "basically the functions of most of the hemodialysis machines." Tr. at 830:8-12. His testimony did not analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim. *Cf. NTP*, 418 F.3d at 1325; *Koito Mfg.*, 381 F.3d at 1152 n.4. Moreover, Fresenius has not identified any testimony from Causey where he specifically analyzes element (a). Fresenius further argues that by identifying the Cobe C3 Manual as invalidating prior art with respect to claims in the '131 patent that are dependent on claim 1, Causey implicitly identified the Cobe C3 Manual as meeting element (a) of claim 1 as well. This argument is vague at best and fails to identify substantial evidence given to the jury as required.

Fresenius also points to the Seratron System, as described in the Seratron Technician's Manual, as meeting the limitations of element (a) of claim 1 of the '131 patent. Reliance on the Seratron Manual, however, is problematic for the reason discussed above with respect to claim 26 (there was no testimony connecting it to the '131 patent). Therefore, Fresenius has not identified substantial evidence supporting the jury's verdict that the claims of the

'131 and '434 patents are invalid because a necessary element of both was not addressed.

4. Motivation to Combine the Claims of the '131 and '434 Patents

Baxter argues that Fresenius failed to meet its burden to show a motivation to combine the claims of the '434 and '131 patents. Fresenius witness Causey testified that the motivation to combine the claims of the '434 and '131 patents came from "Dr. Rau's article teaching touch screens on complex medical machines, including hemodialysis machines and a knowledge of those skilled in the art of touch screens as input devices." Tr. at 822:1-14.

As evidence of a motivation to combine, Fresenius relies heavily upon Dr. Rau's article entitled *Ergonomics and Aspects of Application in Medicine*. The article discusses "proposals regarding more sophisticated and complicated instrument systems" for complex medical devices and describes an anaesthesia information system with a touch screen interface. Dr. Rau testified that his article "gave numerous examples of where you can use [touch screen] technology beneficially," and that "one of the examples which I mentioned was hemodialysis and a hemodialysis machine." Tr. at 598:23-599:2.

Fresenius, however, offers little contention that the Rau article does in fact provide a motivation to combine. The article mentions "extracorporeal dialysis" a single time on page seven (F067208). There is no clear and particular showing, teaching, or motivation to combine the use of touch screen technology with a hemodialysis machine. At most, the Rau article is an "obvious to try" situation: it may have been

obvious to try implementing a touch screen interface together with numerous medical devices, including a hemodialysis machine, but the article in context merely suggests this might be "a promising field of experimentation." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Federal Circuit precedent establishes that where the reference gives only general guidance or a suggested approach, this is insufficient to make the claim "obvious." *See, e.g., In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *O'Farrell*, 853 F.2d at 903 (listing cases).

Turning next to Causey's general citation of the "knowledge of those skilled in the art of touch screens as input devices" this also fails to show a motivation to combine. As specific examples, Fresenius relates the following testimony:

> Mr. Phares testified that by the late 1980s, Elographics was selling "several thousand" touch screen kits per month and was specifically targeting the medical device industry to get them to use touch screens. [*Id.* at 454:6-455:9.] He testified that Elographics "did a significant amount of advertising and participated in—in many trade shows" to encourage the use of touch screens. [*Id.* at 449:25-450:5.]
>
> Perry Guinn, the original project manager for the SATRN project, testified that the SATRN design team "would be getting, on a regular basis, trade magazines that had advertisements for all of the latest, you know, gee-whiz features that were coming along that were available to designers of equipment. And

so [touch screens] were well-known, and—and well—they were very available. They just weren't cheap." [Ex. B, 7/22/2005 Depo. Tr. of Perry Guinn at 44:25-45:7.]

Mr. Kelly testified that the System 1000 used an IBM compatible personal computer [Ex. A, Tr. at 986:10-17; Ex. I, PTX 157 at BA 184055] and conceded that touch screens were one of the well-known user interfaces that could be used to allow a person to interact with a computer [Ex. A, Tr. at 709:6-21.]

Mr. Kelly also testified that using a touch screen could simplify the user interface. [Ex. A, Tr. at 900:4-5 ("by using touch screens, I felt we could potentially simplify the user interface".] Mr. Ferraro then later conceded that it would make sense to make the user input device for a hemodialysis machine as simple as possible for the technician. [Id. at 1274:22-1275:2.]

The Sarns 9000 manual touts the supposed advantages of touch screens. [*See* Ex. J, PTX 342 at F298964 ("The unique S9000 touchscreen allows at-a-glance monitoring of critical information. Additional data can be displayed and manipulated as required, without losing sight of critical values"); *see also* F298967 ("The S9000 integrates advanced pumping technologies with computer-aided monitoring and efficient touchscreen controls for more assured decision-making and top perfusion performance. . . . Critical monitoring information is continuously displayed on the S9000 touchscreen, eliminating the need to

> scroll though menus to access the information needed.").]

Docket No. 860 at 18-19.

The difficulty with this evidence is that it merely demonstrates knowledge of touch screens in prior art. *See, e.g., Smiths Indus. Med. Sys. Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) (emphasis in original) ("That knowledge *may* have been within the province of the ordinary artisan does not in and of itself make it so, absent clear and convincing evidence of such knowledge"). It fails to establish the clear and particular "reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). It is not disputed that the use of touch screens as inputs were known in the art; the issue Fresenius needed to prove was that there was a motivation to combine the touch screen in the manner claimed in the patents. *Id.* ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"). Even knowledge in the prior art of every element of a patent claim is not itself sufficient to render a claim obvious. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1357 (Fed. Cir. 2003); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987). The cited evidence is deficient in this respect for establishing such a motivation to combine the claims of the '131 and '434 patents. Therefore Fresenius has not shown there is substantial evidence adequately supporting the jury's decision on this point.

5. Claim 7 of the '476 Patent

Element (e) of claim 7 of the '476 patent requires "means, responsive to the entered time period and entered proposed profile, for comparing the profile cumulative value with the target cumulative value." Docket No. 835-1 (Jury Instr. at 17). The "means . . . for comparing" is a microprocessor. *See* Docket No. 701, at 30 (Order on Mot. Sum. Judg.). On the CMS 08, it is the user of the machine that does the "comparing" rather than a microprocessor. *Id.* Dr. Richard A. Ward testified on behalf of Fresenius with regard to claim 7. Dr. Ward testified that it would have been obvious to modify the CMS 08 to have the machine perform the "comparing" step of element (e) automatically rather than requiring the user to perform this function. Tr. at 537:11.

Baxter complains that Dr. Ward's testimony was conclusory and failed to identify anything suggesting such a modification, and that his testimony failed to explain how or why one of ordinary skill in the art would have made the modification in 1991. Fresenius counters that it is well known that steps performed manually may be automated using a computer and maintains that the single reference of the CMS 08 was enough to show automatic comparing. This is not persuasive. A broad, conclusory statement that such a modification was "obvious" is not enough to demonstrate by clear and convincing evidence that the teachings of the prior art would have suggested this modification. There must be factual support for an expert's conclusory opinion. *See Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000).

It is true that under some circumstances, a single prior art reference, such as the CMS 08, may be sufficient to render a claim obvious. *See, e.g., SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F 3d 1577, 1582 (Fed. Cir. 1996). However, there must still be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion. *SIBIA*, 225 F.3d at 1356. Dr. Ward's brief testimony failed to address precisely where this suggestion or motivation was found in the prior art.

6. Claim 5 of the '476 Patent

Claim 5 of the '476 patent requires:

A method of providing operational instructions to a dialysate-producing machine having a memory and a capability of ultrafiltrating fluid from a patient according to a timevariable ultrafiltration profile, so as to enable the machine to produce dialysate having particular ultrafiltration characteristics at various times during use of the machine for a dialysis procedure, the method comprising:

> (a) providing a user/machine interface configured as a touch screen operably connected to the dialysate-producing machine;
>
> (b) programming into the memory a first ultrafiltration profile;
>
> (c) providing on the touch screen an indicium enabling a user of the machine

> to recall the first ultrafiltration profile from memory;
>
> (d) using the touch screen, displaying on the touch screen first and second intersecting axes defining a ultrafiltration profile region, the first axis corresponding to ultrafiltration rate, and the second axis corresponding to time; and
>
> (e) touching the indicium provided in step (c) to cause the touch screen to display within the ultrafiltration profile region a second ultrafiltration profile substantially conforming to the first ultrafiltration profile.

Docket No. 835-1 (Jury Instr. at 16).

Dr. Ward opined that claim 5 of the '476 patent is invalid as obvious. Baxter argues that Fresenius was obliged but failed to show that one of ordinary skill in the art would be motivated to combine a touch screen with the CMS 08 to display and control the function described in the elements of claim 5 of the '476 patent. *Cf. Koito*, 381 F.3d at 1151.

Fresenius maintains that it demonstrated that the CMS 08 meets all the elements of claim 5 except for the touch screen. It then notes that Dr. Ward concluded that claim 5 is invalid over a combination of the CMS 08 and a touch screen and that this conclusion is supported by evidence that touch screens "were known as input devices for medical devices at the time the patents were filed." Docket No. 860 at 23.

As related in the discussion of claim 7, when relying on a single reference to prove obviousness,

"there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion." *SIBIA Neurosciences*, 225 F.3d at 1356. Again, Dr. Ward did not offer testimony that the prior art contained a suggestion or motivation to combine the CMS 08 with a touch screen.

Fresenius further relies on the testimony of Phares and Causey with respect to claim 5. Causey testified that it would have been "exceptionally straightforward" to add a touch screen input device to the CMS 08. Tr. at 841:21-25. Phares testified that integrating a touch screen into a computercontrolled machine had been done hundreds of time before. Tr. at 468:13-25. This testimony too fails to show substantial evidence of a motivation to combine. "[O]pinion evidence that is connected to existing data only by the *ipse dixit* of the expert" is of little value. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). More particularly, the motivation to combine must be supported by actual evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002). Nothing beyond conclusory opinions were offered. Therefore, substantial evidence is missing to support the jury findings on claims 5 and 7 of the '476 patent.

7. Claim 11 of the '027 Patent

Baxter maintains that the testimony of Ragsdale and Causey was legally insufficient to prove obviousness of claim 11 of the '027 patent. Baxter contends that Causey addressed only claim 11 of the '027 patent, and reasons that because he did not address the limitations of independent claim

7, upon which claim 11 depends, he therefore failed to examine claim 11 "as a whole" as required by 35 U.S.C. § 103. Baxter also argues that Ragsdale's testimony about the '027 patent was limited to the issue of anticipation, not obviousness.

Fresenius counters that Ragsdale testified unequivocally that claim 7 was anticipated by the Seratron, citing this declaration: "everything that is written here is exactly what the Seratron did." Tr. at 549:2-550:13. And Fresenius reasons that this "anticipation" testimony necessarily extends to obviousness, citing the proposition that "[i]t is well settled that 'anticipation is the epitome of obviousness.'" *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (quoting *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). This legal maxim, however, does little to overcome the statutory requirements of 35 U.S.C. § 282 that

> Each claim of a patent (whether in independent, dependant, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.

Claim 11 is dependent on claim 7. *See* Docket No. 835-1 (Jury Instr. at 18). Accordingly, claim 11 includes claim 7. Thus if 7 was not addressed, then all of the elements of 11 were not addressed. Fresenius therefore did not offer substantial evidence that one of skill in the art would, at the time the inventions were made, have recognized that each limitation of claim 11 were in the prior art or would have

been motivated to combine the prior art. The jury's decision on this issue must be set aside as a result.

B. Motion for a New Trial Pursuant to Rule 59

Baxter has also submitted a Motion for a New Trial Pursuant to Rule 59 [Docket No. 845]. Federal Rule of Civil Procedure 59(a) provides that a "new trial may be granted . . . on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States." FED. R. CIV. P. 59(a). A new trial is appropriate if the verdict is contrary to the clear weight of the evidence, or is based upon evidence which is false, or to prevent, in the sound discretion of the trial judge, a miscarriage of justice. *See Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1005 (9th Cir. 2004); *City Solutions, Inc. v. Clear Channel Communications*, 365 F.3d 835, 843 (9th Cir. 2004). A new trial is generally not granted unless the court "is left with the definite and firm conviction that a mistake has been committed." *Landes Constr. Co. v. Royal Bank of Can.*, 833 F.2d 1365, 1372 (9th Cir. 1987).

In its motion, Baxter seeks a new trial on three issues: (1) the validity of the '434 patent, the '131 patent, the '476 patent, and the '027 patent; (2) on its allegations that the patents were infringed; and (3) damages. As discussed, the jury found that the various claims of the four patents were invalid as either obvious or as anticipated. The Court has determined that the jury's determination of invalidity on the claims is not supported by substantial evi-

dence and accordingly, as a matter of law, must be set aside. Therefore many of the arguments in Baxter's motion for a new trial are rendered moot by the Court's findings on Baxter's motion for judgment as a matter of law. A new trial is appropriate nevertheless.

The jury held that Baxter did not prove by a preponderance of the evidence that the Fresenius 2008K hemodialysis machine literally infringes claim 5 or 7 of the '476 patent. *See* Docket No. 829 (Jury Verdict at 4). The finding of non-infringement necessarily followed the determination of invalidity. As the Court has found that Fresenius has not proven by clear and convincing evidence the invalidity of the patents, the issues of validity, infringement, and possible damages are still left for resolution. A new trial to determine these matters is necessary.

CONCLUSION

IT IS HEREBY ORDERED THAT Baxter's Motion for Judgment as a Matter of Law [Docket No. 847] is GRANTED and that Baxter's Motion for a New Trial Pursuant to Rule 59 [Docket No. 845] is also GRANTED.

IT IS SO ORDERED.

February 12, 2007

Saundra Brown Armstrong
United States District Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.,
Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., et al.,
Defendants.

No. C 03-1431 SBA

ORDER

[Docket Nos. 436, 448]

This matter comes before the Court on Plaintiffs Fresenius Medical Care Holdings, Inc. and Fresenius USA, Inc.'s (collectively, "Plaintiffs" or "Fresenius") Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 and Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion for Partial Summary Judgment of Validity.

Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby GRANTS Motion for Partial Summary Judgment of Validity [Docket No. 448] and DENIES Fresenius'

Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 [Docket No. 436].

BACKGROUND

A. Procedural Background

Plaintiffs and counter-defendants Fresenius USA, Inc.[1] and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter").[2] Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 (the "'434 Patent")[3]; (2) U.S. Patent No. 5,326,476 (the "'476 Patent")[4]; (3) U.S. Patent No. 6,284,131 B1 (the

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[1] Fresenius Medical Care Holdings, Inc. is the country's leading full service provider of dialysis care. Compl. at ¶ 4. Through various affiliates, the company treats approximately 79,600 patients in approximately 1,080 dialysis clinics throughout the United States. *Id.* Fresenius USA, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. and has a research and manufacturing facility in Walnut Creek, California. *Id.*

[2] Baxter Healthcare Corporation and Baxter International Inc. are affiliated corporations that make dialysis machines, equipment, and supplies, which are sold to dialysis clinics. Compl. at ¶ 5.

[3] The '434 Patent was issued on September 21, 1993 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 17.

[4] The '476 Patent was issued on July 5, 1994 and claims an invention entitled "Method and Apparatus for Kidney Dialysis

"'131 Patent")[5]; (4) U.S. Patent No. 5,486,286 (the "'286 Patent")[6]; and (5) U.S. Patent No. 5,744,027 (the "'027 Patent")[7] (collectively "patents-in-suit").

Baxter is the assignee and record owner of the patents-in-suit. Baxter has commercialized the inventions of the patents-in-suit through hemodialysis instruments, such as the Drake Willcock™ System 1000 Dialysate Delivery System ("System 1000"). Amend. Ans. at ¶ 19. On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents.

On October 9, 2003, pursuant to this Court's Patent Local Rules, Baxter served its Preliminary Infringement Contentions.

On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of the '286 Patent.

On November 24, 2003, pursuant to Patent Local Rule 3-3, Fresenius served its Preliminary Invalidity Contentions. After Fresenius filed a Motion to Compel Further Disclosures on December 22,

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Using Machine with Programmable Memory." Amend. Ans. at ¶ 26.

[5] The '131 Patent was issued on September 1, 2001 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 35.

[6] The '027 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 46.

[7] The '286 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Performing a Self-Test of Kidney Dialysis Membrane." Amend. Ans. at ¶ 55.

2003, Baxter served supplemental infringement contentions.

On October 14, 2004, a claim construction hearing was held on certain disputed terms. After the Court issued its claim construction ruling on November 22, 2004, the parties met and conferred in order to narrow the selection of additional terms to be construed by the Court.

On December 28, 2004, Baxter served its Final Infringement Contentions pursuant to Local Rule 3-6(a).

On January 5, 2005, Baxter filed a Motion for Partial Summary Judgment of Infringement with respect to claim 1 of the '131 Patent and claim 26 of the '434 Patent.

On January 6, 2005, the parties requested that the Court construe one additional claim term from claim 26(a) of the '434 Patent: "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration."

On January 18, 2005, Fresenius served its Final Invalidity Contentions pursuant to Patent Local Rule 3-6(b). In its Final Invalidity Contentions, Fresenius identified the Sarns 9000, including its operation manuals, as invalidating prior art.

On February 15, 2005, Fresenius filed a Cross-Motion for Summary Judgment with respect to whether Fresenius infringed claim 1 of the '131 Patent and claim 26 of the '434 Patent. Also on February 15, 2005, Baxter filed a Motion to Strike Fresenius' Final Invalidity Contentions.

On March 1, 2005, this Court issued an order construing the remaining disputed claim term in claim 26(a) of the '434 patent.

On August 24, 2005, the Court issued an Order denying Baxter's Motion to Strike Fresenius' Final Invalidity Contentions.

On September 2, 2005, this Court issued an Order granting in part and denying in part Baxter's Motion for Partial Summary Judgment and granting and denying in part Fresenius' Cross-Motion for Summary Judgment. The Court held that Fresenius' 2008K hemodialysis machine infringed claim 26 of the '434 Patent and claim 1 of the '131 Patent. The Court also held that the SVS, Kt/V and Blood Pressure screens of the 2008K did not infringe claim 1 of the '131 Patent.

On February 21, 2006, Fresenius filed the instant Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131, seeking partial summary judgment that: (1) the asserted claims of the '434 and '131 Patents are invalid as obvious under U.S.C. § 103(a); (2) the asserted claims of the '131 Patent are invalid as anticipated under 35 U.S.C. § 102(b) by the Sarns Manual; and (3) the touch screen claims[8] of the patents-in-suit are invalid for failure to satisfy the enablement and best mode requirements of 35 U.S.C. § 112. With respect to its obviousness defense, Fresenius requests that the Court enter summary judgment in its favor on the grounds that the '434 and '131 Patents are rendered obvious by the following prior

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[8] The asserted "touch screen" claims are claims 26-31 of the '434 Patent, claims 1-3 and 13-16 of the '131 Patent, claim 5 of the '476 Patent, and claim 11 of the '027 Patent.

art references: (1) the Sarns Manual; (2) U.S. Patent No. 4,756,706 issued to Kerns (referred to herein as "Kerns" or the "Kerns patent"); (3) U.S. Patent No. 4,898,578 issued to Rubalcaba (referred to herein as "Rubalcaba" or the "Rubalcaba patent"); and (4) U.S. Patent No. 4,370,983 issued to Lichtenstein (referred to herein as "Lichtenstein" or the "Lichtenstein patent").

Also on February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial summary judgment that: (1) claim 5 of the '476 Patent and claim 11 of the '027 Patent are invalid as obvious under 35 U.S.C. § 103(a); (2) claim 7 of the '476 Patent and claims 1, 2, 4, 6-8, 10, and 12-16 of the '027 Patent are invalid as anticipated under 35 U.S.C. § 102(b); and (3) claim 5 of the '476 Patent is invalid for failure to satisfy the definiteness and enablement requirements of 35 U.S.C. § 112.

On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity, seeking judgment that the asserted claims of the '434 and '131 Patents are not invalid under 35 U.S.C. § 102 for anticipation, and that the asserted claims of the '434, '131, '027, and '476 Patents do not violate the best mode and enablement requirements of 35 U.S.C. § 112.

Also on March 7, 2006, Baxter filed the following motions: (1) a Motion to Bar Fresenius' Proffered Damages Expert Professor Rubinfeld; (2) a Motion to Strike Fresenius' Best Mode and Anticipation Defenses, in Part, Under Local Rule 3-7; and (3) a Motion to Bar the Expert Testimony of Jeff Riley.

On March 14, 2006, pursuant to a stipulation between the parties, the Court issued an Order dis-

missing with prejudice: (1) all claims, counterclaims, and defenses of the parties concerning the '286 Patent and claims 1 and 6 of the '476 Patent; (2) all claims, counterclaims, and defenses of the parties concerning Fresenius' 2008H hemodialysis machine; (3) Fresenius' affirmative defenses of laches, estoppel, failure to mark, and prosecution laches with respect to all of the patents-in-suit; (4) Fresenius' affirmative defense of unenforceability with respect to the '286 Patent and the '027 Patent; (5) Fresenius' defense of improper inventorship based on alleged contribution by Ziba Design with respect to all of the patents-in-suit; (6) Fresenius' defense of indefiniteness as to claims 1, 13 and 14 of the '131 Patent.

On March 21, 2006, Fresenius filed its Oppostion to Baxter's Motion for Partial Summary Judgment of Validity, attaching in support several declarations, including a declaration from Richard Alan Griewski. Also on March 21, 2006, Baxter filed the following motions: (1) a Motion to Strike the Declaration of Charles Ragsdale; (2) a Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary Judgment of Invalidity of '434 and '131 Patents; and (3) a Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of '476 and '026 Patents.

On March 28, 2006, Baxter also filed a Motion to Strike the Declaration of Richard Alan Griewski.

B. Factual Background

1. Hemodialysis

Dialysis is a process in which solutes transfer from one fluid compartment to another across a semi-

permeable[9] membrane. Ward Decl. at ¶ 10. In hemodialysis, the semipermeable membrane is contained in a device known as a dialyzer and the two fluid compartments are the blood and the dialysate, a man-made solution containing the major ionic constituents of blood. *Id.* To perform hemodialysis, a patient's blood is taken from the bloodstream and circulated through the dialyzer – which is sometimes referred to as an artificial kidney – where it undergoes purification. *Id.* The urea and other waste metabolites are removed through a process known as diffusion. *Id.* at ¶ 11. The purified blood is then returned to the patient's blood stream and the dialysate, containing the waste products, is discarded. *Id.* at ¶ 10.

Another principal function of hemodialysis is to remove the fluid consumed by the patient between dialysis treatments. *Id.* at ¶ 12. Fluid is removed by creating a pressure difference between the blood and dialysate sides of the dialyzer membrane so that fluid flows from the blood to the dialysate. *Id.* The rate of fluid flow depends on the pressure difference and the water permeability of the dialyzer membrane. *Id.*

In the beginning of the 1980's, hemodialysis machines consisted of simple electro-mechanical systems and changes in operating parameters during the course of treatment required an action by the operator. *Id.* at ¶ 16. However, when it was realized that some of the adverse symptoms patients experienced during dialysis could be ameliorated by varying the operating parameters during dialysis, hemo-

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[9] A semipermeable membrane is one which allows free passage of small solutes, but which is impermeable to large solutes. *Id.*

dialysis machines began to incorporate microprocessor-based ultrafiltration control systems. *Id* at ¶¶ 14, 16. Microprocessor-based control systems control the dialysate compartment pressure to achieve the desired ultrafiltration rate. *Id.* at ¶ 16. Microprocessor systems have the benefit of allowing many of the previously manual safety monitoring and alarm operations, such as pre-treatment testing of the integrity of the ultrafiltration control system and calculating predicted dialysate conductivity, to be automated, thereby making dialysis safer and more reliable. *Id.* The incorporation of a battery-based backup system also allowed important treatment parameters to be stored in the case of a power failure. *Id.*

Two strategies were also developed and incorporated into hemodialysis machines to address problems relating to fluid removal that occasionally occurred during hemodialysis. *Id.* at ¶ 17. These strategies were based on: (1) varying the rate at which fluid was removed during dialysis, which is known as ultrafiltration profiling;[10] and (2) varying the sodium concentration in the dialysate throughout

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[10] The extent to which ultrafiltration affects blood pressure is determined, in part, by how rapidly excess fluid from other parts of the body enters the blood stream. Id. at ¶ 18. Ultrafiltration profiling allows fluid removal to be increased during times of rapid vascular refilling and decreased when vascular refilling is slow. Id. at ¶ 18.

the treatment, which is known as sodium profiling.[11] *Id.* Both ultrafiltration profiling and sodium profiling were made possible by the development of ultrafiltration control systems, more sophisticated dialysate proportioning systems, and the incorporation of more advanced microprocessor technology into dialysis machines. *Id.*

To perform ultrafiltration profiling, the speed of the ultrafiltration pump is varied as a function of treatment time according to some predetermined scheme. *Id.* at ¶ 19. In general, the volume of fluid prescribed for removal varies from one treatment to the next, even for the same patient. *Id.* Thus, for ultrafiltration to be generally applicable, the computer controlling ultrafiltration must be able to adjust the absolute ultrafiltration rates associated with a given ultrafiltration profile to match the desired fluid removal target for a particular treatment. *Id.*

In sodium profiling, a higher sodium concentration is used in the dialysate at the beginning of the hemodialysis treatment so that the sodium enters the blood and maintains osmotic pressure. *Id.* at ¶ 20. Later in the dialysis process, after most urea removal has taken place, the dialysate concentration is decreased to remove the added sodium. *Id.* To per-

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[11] Rapid rates of solute removal have the effect of driving water out of the blood into other body compartments as the body attempts to maintain osmotic equilibrium between the different water pools in the body. *Id.* at ¶ 20. This movement of water opposes vascular refilling and can decrease blood volume and blood pressure, particularly if fluid is also being removed from the blood via a dialyzer. *Id.* Sodium profiling is a means of maintaining osmotic equilibrium and maintaining patient blood volume. *Id.*

form sodium profiling, the speed of the concentrate pump is manipulated to proportion more or less concentrate to fit a predetermined time-dependent sodium concentration profile. *Id.* This process requires a mechanism to monitor and change the sodium concentration throughout the treatment, which requires the entry of additional non-conductivity data. *Id.* at ¶ 21. When sodium profiling is used, the chemical composition and non-conductivity data is used in conjunction with an algorithm programmed into the computer which calculates the expected conductivity[12] of the dialysate at a particular point in the dialysis treatment and adjusts the conductivity alarm limits. *Id.*

Another feature that was eventually incorporated into hemodialysis machines was the addition of a "touch screen user interface." Touch screen user interfaces typically consist of hardware components and software components. Causey Decl. ISO Opp. to Baxter's MSJ at ¶ 16. The hardware components include a display, a touch screen that overlays the display, and associated electronics such as a touch screen controller. *Id.* at ¶ 17. The display – which is typically a CRT, LCD, or plasma display – displays images, numbers, and other information to the user. *Id.* at ¶ 18. The touch screen overlays the display and is touch-sensitive to allow the user to input information to control the device to which the touch

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[12] Conductivity is defined as the ability of a solution to pass electrical current. 131.18:25-30. Conductivity is used as a measurement of the electrolyte composition of the dialysate. *Id.* The conductivity of dialysate varies due to the temperature and the electrolyte composition of the dialysate. *Id.*

screen user interface is connected. *Id.* at ¶ 19. The touch screen controller sends signals to the device indicating where on the touch screen overlay the user touched. *Id.* at ¶ 20. The touch screen controller is usually purchased from the supplier of the touch screen overlay. *Id.* at ¶ 20. As to the software, this is necessary to tell the device how to operate. *Id.* at ¶ 20. In the case of hemodialysis machines, the software – which runs in one or more of the microprocessors – controls the various pumps, valves, heaters, and other components of the hemodialysis machines. *Id.* at ¶ 21. The software also causes images to be created in simple or complex forms on the display portion of the touch screen user interface. *Id.* at ¶ 22. The operator of the machine responds to the images by touching the touch screen overlay, causing analog signals to be converted to digital representations as inputs to the software. *Id.* The software therefore provides the "instructions" to the hemodialysis machine for drawing images, buttons, and numbers presented on the display, reacting to the touching of the touch screen, and changing the operating behavior of the machine. *Id.*

2. Description of the '434 and '131 Patents

The patents-in-suit disclose and claim various improvements to hemodialysis machines that allow better control, operation and monitoring of hemodialysis treatment. *See* 434:Abstract, 1:5-8, 131:Abstract, 1:12-15.[13] For example, the patents-in-

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[13] References to the '131 and '434 Patents are cited herein as "XXX.YY" with "XXX" denoting the patent number and "YY"

suit improved upon prior art dialysis machines by developing a new computer-controlled system that controls and monitors key functions such as dialysate preparation, ultrafiltration removal, and blood monitoring. 434:Abstract. The '434 and '131 Patents claim dialysis machines with user/machine interfaces. *See*, e.g., 434.26; 131.1. The '131 Patent and '434 Patent also disclose integrating a touch screen interface through which treatment parameters can be set, monitored, and changed. *See* 131.1, 434.26.

The '434 Patent is the parent application covering the particular use of a user/machine interface with a dialysis machine. *See* 434.26. The '131 Patent builds upon this technology by describing the ability to profile dialysis treatment parameters through the user/machine interface. *See* 131.1.

The only independent claims of the '434 and '131 Patents that Baxter has asserted against Fresenius are claim 26 of the '434 Patent and claim 1 of the '131 Patent, both of which are reproduced below.

Claim 26 of the '434 Patent requires:

> 26. A hemodialysis machine comprising:
> (a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and (b)

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denoting the claim number (*e.g.*, Claim 1 of the '131 Patent is "131.1.") or "XXX.YY:ZZ" with "XXX" denoting the patent number, "YY" denoting the claim, and "ZZ" denoting the line (*e.g.*, Claim 1 of the '131 Patent at lines 1 through 10 is "131.1.1-10.").

> a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

434.26.

Pursuant to the Court's *Markman* Orders and the parties' agreed-upon claim constructions, the "means for controlling" limitation of claim 26 requires a microprocessor and either: (1) a heater and a temperature-sensing device; or (2) a concentrate pump. Additionally, the "means for delivering" limitation of claim 26 requires a supply pump. Part (b) of claim 26 requires "a touch screen adapted . . . to permit the user, by touching the indicium, to effect a change in the parameter."

Claim 1 of the '131 Patent requires:

> 1. A hemodialysis apparatus, comprising:
>
> (a) a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and

> (b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis apparatus, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.

131.1.

As construed, part (b) of claim 1 requires that only one step of the procedure occur on the touch screen. Part (b) further requires: "(1) that the touch screen be operable to display a time-variable set of data of the operational parameter mentioned earlier in the claim, and (2) that this set of data be 'representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.'"

The remaining asserted claims are dependent on the above independent claims and recite various additional hemodialysis machine features.

3. Prosecution History of the '434 and '131 Patents and Other PTO Proceedings

a. The '434 Patent

The '434 Patent application was filed on April 19, 1991. Before allowing the Patent, the examiner considered numerous prior art references, including U.S. Patent No. 4,366,061 and U.S. Patent No. 4,209,391, both of which disclose microprocessor-based hemodialysis machines. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Exs. 1, 2. The examiner also considered a number of touch screen references, including the Kerns patent, the Rubalcaba patent, and U.S. Patent Nos. 5,056,059 (the "Tivig" patent), 4,916,441 (the "Gombrich" patent), 4,873,623 (the "Lane" patent), and 4,914,624 (the "Dunthorn" patent). *See id.* at Exs. 4, 5. Both the Tivig and Gombrich patents disclose touch screens incorporated into medical devices. In a September 1992 office action, the PTO allowed certain claims of the '434 Patent, but rejected others as obvious in view of Kerns. *Id.* at Ex. 6. In response, the applicants amended the claims and argued that Kerns did not render them obvious. *Id.* at Ex. 7. The Examiner agreed, and on September 21, 1993, the '434 Patent issued.

b. The '131 Patent

The '131 Patent application was filed on October 12, 2000. Before allowing the patent claims, the examiner considered the Lichtenstein patent, the CMS 08 Handbook, the Kerns patent, and the Rubalcaba patent. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 8.

On March 3, 2001, the examiner issued a Notice of Allowability. *Id.* at Ex. 10. The Examiner's Reasons for Allowance showed that he considered the teachings of Kerns and Rubalcaba:

> Kerns . . . and Rubalcaba each constitute medical infusion systems in which touch screen interfaces at least partly controlled in put to computerized control systems; however each lacking any suggestion of the screen being operable to allow an operator to change the setting of a parameter of the type representable as a plot of coordinates with respect to an ordinate of parameter values and a time based abscissa.

Id.

On September 4, 2001, the '131 Patent issued.

c. The '240 Application

In 1992, a PTO examiner found Baxter's U.S. Patent Application No. 09/711,240 ("'240 Application") unpatentable under 35 U.S.C. § 103.6 due to the combination of the Lichtenstein patent with either the Kerns patent and/or the Rubalcaba patent. *See* Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 12. The rejected claim of the '240 Application that is relevant to the instant litigation, claim 41, reads as follows:

> 41. A hemodialysis machine, comprising:
>
> (a) means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and
>
> (b) a user/machine interface operably connected to said means for controlling the dialysate parameter, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine and to permit the user, by touching the indicium, to cause a change in the parameter.

See McClenahan Decl. at Ex. 32.

The Final Rejection was issued on April 11, 2002. *See id.* at Ex. 11. Thereafter, Baxter appealed the Final Rejection to the Board of Patent Appeals and Interferences (the "Board"). *Id.* The two issues on appeal before the Board were: (1) whether the examiner properly established a prima facie case of obviousness based on Lichtenstein combined with Kerns and/or Rubalcaba; and (2) whether the available objective evidence of secondary considerations submitted at that time overcame the examiner's obviousness rejection. *Id.* In reviewing the appeal, the Board considered the following evidence of secondary considerations: (1) a declaration from Dr. John

Sadler, and (2) four articles mentioning industrial design awards received by the System 1000. McClenahan Decl. ISO Fresenius MSJ I at Ex. 1. The Board did not hear live testimony from witnesses or consider third-party discovery.

In August 2003, the Board affirmed the examiner's rejection based on the specific combination of Lichtenstein with either Kerns and/or Rubalcaba. *Id.* The Board further found that the evidence of secondary considerations was insufficient to overcome the Examiner's obviousness rejection. *Id.*

Following the adverse decision by the Board, Baxter had the option to: (1) appeal to the Federal Circuit under 35 U.S.C. § 141; (2) bring a civil action against the director of the PTO in the United States District Court for the District of Columbia under 35 U.S.C. § 145; or (3) file a continuation application under 37 C.F.R. § 1.53(b). *See In re Kaghan*, 387 F.2d 398, 400-401 (C.C.P.A. 1967). Baxter chose to file a continuation of the '240 Application within the time allowed to appeal the adverse decision by the Board. *See* 37 C.F.R. § 1.304(a)(1). Claim 41 of the '240 Application became claim 53 of U.S. Patent Application No. 11/175,072 (the "'072 Application"). Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 13.

On September 20, 2005, claim 53 of the '072 Application was rejected under 35 U.S.C. § 103(a) as obvious in light of Lichtenstein, Rubalcaba, and/or Kerns. *See* March 28, 2006 McClenahan Decl. at Ex. C.

d. The '322 Application

In June 2005, the Patent Office issued a "non-final" decision rejecting claim 37 of Baxter's U.S.

Patent Application No. 10/461,322 (the '322 Application), which claims priority to the '434 patent. McClenahan Decl. ISO Fresenius MSJ I at Ex. 2. Claim 37, which was the only pending claim of the '322 Application, provides as follows:

> 37. A method for the use of a dialysis apparatus comprising:
>
> Providing a dialysis apparatus for use in dialysis to a consumer, the dialysis apparatus comprising a dialysate-delivery system for supplying dialysate to a dialyzer, the dialysate-delivery system comprising at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit; and
>
> a user/machine interface operably connected to the dialysate delivery system, the user/machine interface comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the dialysis apparatus, the touch screen being operable to display and indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the op-

> erational parameter and a time-based abscissa; and
>
> providing supplies that are useable with the dialysis apparatus to the consumer, the supplies including at least one of a dialyzer, a blood line, a syringe for withdrawing samples of dialysis solution from a dialysate line sample port, a syringe for a heparin pump, a hydrophobic transducer protector to place on pressure fittings, saline, a dialysate filter, dialysate concentrate, a drip chamber, a dialysate meter for testing dialysate, and a disinfectant.

See Fresenius MSJ I at 3.

The rejection of claim 37 was based in part on a prior art reference entitled the "Sarns® 3M 9000 Perfusion System Operators Manual" (hereinafter referred to as the "Sarns 9000" or the "Sarns Manual"). McClenahan Decl. ISO Fresenius MSJ I at Ex. 2.

e. The Reexamination Proceedings

On September 26, 2005, Fresenius filed a request for reexamination of the '131 Patent. *See* McClenahan Decl. ISO Fresenius MSJ I at Ex. 19. On October 18, 2005, Fresenius requested reexamination of the'434 Patent. *Id.* at Ex. 20. The Patent Office granted the requests on November 22, 2005 and January 5, 2006, respectively. *See id.* at Exs. 21, 22.

4. The Sarns 9000

The Sarns 9000 is a touch screen-controlled perfusion system, also known as a heart-lung machine. McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. J (Sarns Manual at F298967). The Sarns 9000 was offered for sale and sold as of 1988. McClenahan Decl. at Ex. O (Griewski Depo. at 143:15-17); *see id.* at Ex. J (Sarns Manual at F298974).

Perfusion systems such as the Sarns 9000 are intended to substitute for the heart and lungs of a patient who is undergoing cardiopulmonary bypass ("CPB") or valve surgery when the patient's heart must be stopped temporarily. *Id.* at Ex. J (Sarns Manual at F298979); Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 222-23). Using a heart-lung machine, a perfusionist diverts the patient's blood away from the body to an extracorporeal oxygenator, which removes carbon dioxide, oxygenates the blood, and then returns it to the patient. Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 185, 222-24).

The Sarns 9000 includes a touch screen user interface that displays data and operational parameters in both numerical and graphical formats, as illustrated by the "Main" and "Pulsatile" screens. The user can touch indicia on the touch screen to change the settings of the parameters. *Id.* at Ex. J (Sarns Manual at F298971, F299010-14, F299054-55). For example, the user can touch the "Pulse" button on the "Main" screen of the Sarns System to display the "Pulsatile" screen. *Id.* at Ex. J. (Sarns Manual at F299014).

Using the Pulsatile[14] screen, a user of the Sarns 9000 can set the pump speed to emulate the "pulsatile" pumping of the human heart. *Id.* at Ex. J (Sarns Manual at F299054-55). Specifically, the user can control, using the up and down arrows: (1) the number of pump cycles per minute (the "Rate" field); (2) the proportion of time the pump is at the higher output setting (the "Width" field); and (3) the pump speed during the lower output setting as a proportion of the pump speed during the higher output setting (the "Base" field). *Id.* In addition, the user can set the average volume of blood flow per unit time (the "Flow" field). *Id.* Once all of the components of pulsatile flow are entered, a square waveform is then displayed on the touch screen of the Sarns 9000 which graphically depicts the relationship between the maximum and minimum pumping phases of the pulsatile pump. *Id.*

The Sarns 9000 also includes five interchangeable roller pumps designed to offer the user flexibility to configure a variety of extracorporeal and drug delivery circuits as required by individual patients undergoing bypass procedures. *Id.* at Ex. J (Sarns Manual at F299036-F299045). Any one of the disclosed roller pumps is controllable via the touch screen interface and is capable of circulating fluids at controlled rates. *Id.* at Ex. J (Sarns Manual at F298871, F298978-79, F298986-87, F299061-62); *see also* Riley Decl. at ¶ 6.

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[14] Pulsatile flow is a type of blood flow that simulates the beating of the heart sometimes used during a cardiopulmonary bypass procedure when a patient's heart is stopped. See Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 221-22).

The Sarns Manual states that the machine's use is for cardiopulmonary by-pass procedures ("CPB") only. In fact, it explicitly lists as "Indications" the following:

> The Sarns 9000 Perfusion System is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary by-pass procedures, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment.

Abernathy Decl. ISO Baxter MSJ at Ex. 3 (Sarns Manual at F298979).

According to Fresenius' expert, Mr. Griewski, the Sarns Manual does not disclose that the Sarns 9000 can function as a hemodialysis machine or perform functions related to hemodialysis. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 216-18).

LEGAL STANDARD

A. Legal Standard For Summary Judgment in Patent Disputes

Under Federal Rule of Civil Procedure 56, a court may properly grant a motion for summary judgment if the pleadings and materials demonstrate that there is "no genuine issue as to any material fact and the moving party is entitled to judgment as

a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment may be granted in favor of a defendant on an ultimate issue of fact where the defendant carries its burden of "pointing out to the district court that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325; *see Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989).

To withstand a motion for summary judgment, the non-movant must show that there are genuine factual issues which can only be resolved by the trier of fact. *Anderson*, 477 U.S. at 250. The nonmoving party may not rely on the pleadings but must present specific facts creating a genuine issue of material fact. *T.W. Elec. Serv. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987). The court's function, however, is not to make credibility determinations. *Anderson*, 477 U.S. at 249. The inferences to be drawn from the facts must be viewed in a light most favorable to the party opposing the motion. *T.W. Elec. Serv.*, 809 F.2d at 631.

It is not the task of the district court to scour the record in search of a genuine issue of triable fact. *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir. 1996). The nonmoving party has the burden of identifying with reasonable particularity the evidence that precludes summary judgment. *Id.* If the nonmoving party fails to do so, the district court may properly grant summary judgment in favor of the moving party. *See Carmen v. San Francisco Unified School District*, 237 F.3d 1026, 1028-29 (9th Cir. 2001) (even

if there is evidence in the court file which creates a genuine issue of material fact, a district court may grant summary judgment if the opposing papers do not include or conveniently refer to that evidence). Although the district court has discretion to consider materials in the court file not referenced in the opposing papers, it need not do so. *Id.* at 1029. "The district court need not examine the entire file for evidence establishing a genuine issue of fact." *Id.* at 1031. However, when the parties file cross-motions for summary judgment, the district court must consider all of the evidence submitted in support of both motions to evaluate whether a genuine issue of material fact exists precluding summary judgment for either party. *The Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1135 (9th Cir. 2001).

A court may grant a summary judgment motion in a patent case, as in any other case. *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). In fact, the Federal Circuit has expressly recognized that summary judgment of invalidity is proper, including invalidity based on obviousness under 35 U.S.C. § 103. *See, e.g., McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1367 (Fed. Cir. 2003) (affirming grant of summary judgment of invalidity based on obviousness). But "in considering the [summary judgment] motion, the court must view the evidence in the most favorable light to the non-movant and draw all reasonable inferences in the non-moving party's favor." *Tillotson, Ltd. v. Walbo Corp.*, 831 F.2d 1033, 1037 (Fed. Cir. 1987).

Since summary judgment must be supported by "facts as would be admissible in evidence," *see*

Fed. R. Civ. P. 56(e), scientific evidence produced in support of or in opposition to a motion for summary judgment must meet the standards of relevance and reliability articulated in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See Seaboard Lumber Co. v. United States,* 308 F.3d 1283, 1301 (Fed. Cir. 2002). The Supreme Court in *Daubert* described this inquiry as follows:

> Faced with a proffer of expert scientific testimony . . . the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. at 590.

B. Invalidity

Patents are presumed to be valid and the burden of establishing the invalidity of a patent rests on the party asserting invalidity. *See* 35 U.S.C. § 281. The factual findings supporting a conclusion of invalidity must be proven by clear and convincing evidence. *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1151 (Fed. Cir.1987).

1. Legal Standard for Anticipation

A patent claim is invalid as anticipated if "the invention was patented or described in a printed publication in this . . . country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharmas.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). A prior art reference may, however, anticipate "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *see also Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

In determining invalidity due to anticipation, the first step involves the proper interpretation of the claims. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir.1995). To ascertain the meaning of the claims, the court looks to the claim language, the specification, and the prosecution history. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1989). The other claims and expert testimony are also relevant. *Id.* "The claims should be construed as one skilled in the art would construe them." *Id.*

The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art. *Id.* "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference." *Scripps Clinic & Research Fdn. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir.1991) ("There must be no difference between the claimed invention

and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention"); *Hazani v. U.S. Intern. Trade Com'n*, 126 F.3d 1473, 1477 (Fed.Cir.1997).

An anticipation analysis involves a three-part inquiry. First, the trier of fact must determine whether the challenging reference is prior art. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-78 (Fed. Cir. 1996); *Del-mar Eng'g, Lab v. United States*, 524 F.2d 1178, 1184 (Ct. Cl. 1975). Second, the fact finder must ascertain that the prior art is enabling as to put the invention in the public's possession. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F .2d 1471, 1479 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). However, prior art patent references are presumed enabled. *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A.1980). In the third step, the trier of fact must ascertain whether the doctrine of identity applies, *i.e.*, whether each element of the accused claim is present either expressly or inherently in a single prior reference. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed.Cir.1983), *cert. denied*, 465 U .S. 1026 (1984).

2. Legal Standard for Obviousness

Pursuant to 35 U.S.C. § 103, patent claims are invalid "if the differences betwe n the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "It is black letter law that the ultimate question of obviousness is a question of law." *Richardson-Vicks*, 122 F.3d at 1479.

An obviousness analysis is based on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of nonobviousness, such as commercial successs, copying, or long felt but unresolved need in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness can include commercial success, long felt but unresolved need, and failure of others to solve the problem. *Id.*; *see also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Such considerations are not material to the issue of invalidity, however, unless there is a nexus between the evidence and the features described in the claims. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Precedent also requires a suggestion, teaching, or motivation to combine the references relied upon, or to modify a single reference such that the claimed invention is practiced. *Brown & Williamson*, 229 F.3d at 1124-25. Evidence of a motivation to combine "may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or in some cases, from the nature of the problem to be solved." *Id.* at 1125 (citing *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996)).

3. Legal Standards for Enablement and Best Mode

A patent grant is issued in exchange for an enabling disclosure of an invention. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788,

791 (Fed. Cir. 1983). The enablement requirement of 35 U.S.C. § 112, paragraph 1, provides, in relevant part, that:

> The [patent] specification shall contain a written description of the invention, and the manner and process of making and using the [invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the [invention].

35 U.S.C. § 112.

The enablement requirement is met "when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Enablement is a question of law based on underlying facts, which is tested as of the effective filing date of the application. *Id.*

Enablement is determined at the time the patent application was filed. *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 1019 (2001). Determining whether a disclosure of a patent satisfies the enablement requirement is a question of law. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). The legal conclusion of enablement rests on factual underpinnings. *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690 (Fed. Cir. 2001).

A decision on the issue of enablement "requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the claimed invention without undue experimentation." *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *Enzo Biochem v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

While some experimentation does not preclude enablement, the amount of experimentation must not be unduly extensive. *Atlas Powder Co.*, 750 F.2d at 1576. The test for undue experimentation allows for a considerable amount of experimentation if it is merely routine or if the patent specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

35 U.S.C § 112 also contains a best mode requirement. Specifically, section 112 requires that the inventors "shall set forth the best mode contemplated by the inventor in carrying out his invention." The purpose of the best mode requirement is "to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the in-

ventor a full disclosure of the preferred embodiment of the invention." *Dana Corp. v. IPC Ltd. P'ship*, 860 F.2d 415, 418 (Fed. Cir. 1988). A party challenging the validity of a patent based on best mode must establish, by clear and convincing evidence, that the inventors concealed the best mode known to them of practicing the claimed inventions. *High Concrete Structures, Inc. v. New Enterprise Stone & Lime Co., Inc.*, 377 F.3d 1379, 1382 (Fed. Cir. 2004).

Invalidation for failure to describe the best mode requires the Court to determine whether: (1) the inventor knew of a better mode than was disclosed; and (2) the inventor intentionally concealed that better mode. *Id.* at 1382-83; *Bayer AG v. Schein Pharmaceuticals Inc.*, 301 F.3d 1306, 1320 (Fed. Cir. 2002). "It is concealment of the best mode of practicing the claimed invention that [35 U.S.C. § 112(1)] is designed to prohibit." *Randomex Inc. v. Scopus Corp.*, 849 F.2d 585, 588 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) ("In order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed."). The best mode requirement is not violated by the unintentional omission of information that would be readily known to persons in the field of the invention. *High Concrete Structures, Inc.*, 377 F.3d at 1383.

ANALYSIS

A. Anticipation

In its Motion for Partial Summary Judgment, Baxter requests that the Court enter judgment in its

favor on Fresenius' anticipation affirmative defense. Specifically, Baxter asks the Court to find that claims 26-31 of the '434 Patent and claims 1-3 and 13-16 of the '131 Patent are not anticipated by the Sarns 9000. In its own Motion for Summary Judgment, Fresenius asks the Court to find that the '131 Patent is anticipated by the Sarns 9000 as a matter of law. Although considered a question of fact, anticipation is appropriate for summary judgment if no genuine issue of material fact exists. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001) (affirming summary judgment of invalidity where "no reasonable jury could find" the patent valid in light of the prior art).

As a preliminary matter, the Court notes that Fresenius has not separately moved for a summary judgment finding of anticipation with respect to the '434 Patent and specifically states in its Opposition to Baxter's Motion that it is *not* arguing that the '434 Patent is anticipated by the Sarns 9000 because "the asserted claims [of the '434 Patent] include one or more means-plus-function limitations which, properly construed, are not fairly met by the Sarns System alone." Accordingly, the Court hereby GRANTS summary judgment in Baxter's favor and find that the '434 Patent is not anticipated by the Sarns 9000.

With respect to the asserted claims of the '131 Patent, Fresenius bears the burden of proving by clear and convincing evidence "strict identity" between the claimed invention and the Sarns 9000 such that ***each and every*** claim limitation is described in the reference. *Trintec Indus., Inc. v. TOP-U.S.A. Corp.*, 295 F.3d 1292, 1295-96 (Fed. Cir. 2002); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 994-95 (Fed. Cir. 2000). If there is even

one claim element missing in the Sarns 9000, Fresenius' invalidity defense fails and Baxter is entitled to summary judgment.

To meet its burden, Fresenius asserts that part (a) of claim 1 of the '131 Patent,[15] which recites a "dialysate-delivery system for supplying dialysate to a hemodialyzer," is only an intended use or function of the patent and not a structural limitation. Fresenius further contends that the asserted claim limitation merely requires a system, such as a pump, capable of supplying dialysate to a hemodialyzer when a hemodialyzer is connected to the system and that the Sarns 9000 fully meets this claim limitation.[16]

In response, Baxter argues that Fresenius' anticipation defense fails for the following reasons: (1) claim 1 of the '131 Patent requires "a hemodialysis apparatus" which, pursuant to the parties' agreed upon construction, is a "kidney dialysis machine that removes metabolic waste from the patient's blood by

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[15] The parties focus on claim 1 of the '131 Patent because it is the only independent claim and because dependent claims are not anticipated, as a matter of law, if the claim upon which they depend is not. *See Hartness Int'l v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108 (Fed. Cir. 1987).

[16] Specifically, in Fresenius' third supplemental response to Interrogatory No. 6 Regarding Invalidity, Fresenius states that: "Performance of hemodialysis during bypass simply require[s] the addition of a dialyzer to the extracorporeal circuit of the perfusion system and the use of one of the roller pumps of the perfusion system to circulate dialysate to the dialyzer. The system disclosed by the Sarns System is inherently capable of accepting a dialyzer in its extracorporeal circuit and using one of its five touch screen controlled roller pumps to circulate dialysate to the dialyzer." *See* Abernathy Decl. ISO Baxter MSJ at Ex. 7.

circulating the blood through an extracorporeal circuit"; (2) claim 1 requires a number of hemodialysis-specific features; (3) the Sarns Manual does not disclose that the Sarns 9000, a heart-lung machine, can function as a"hemodialysis apparatus," and the Manual does not disclose that the Sarns 9000 can perform any of the hemodialysis-specific functions required by the claims; (4) the Sarns 9000 does not have a "time-variable profile" and a "time-based abscissa" required by claim 1 of the '131 Patent; and (5) the secondary articles cited by Fresenius are outside of the "four corners" of the Sarns Manual and therefore fail to render the Sarns 9000 a hemodialysis machine.

The Court finds Baxter's arguments persuasive and, as set forth in greater detail below, Baxter has convincingly established that it is entitled to summary judgment on this anticipation defense.

1. Interpretation of the Claims

The first step in determining validity due to anticipation involves the proper interpretation of the claims. *Elmer*, 67 F.3d at 1574. Accordingly, this Court must first address whether claim 1 of the '131 Patent requires a "hemodialysis apparatus." To ascertain the meaning of a patent claim, a court may look to the claim language, the specification, and the prosecution history. *SmithKline Diagnostics, Inc.*, 859 F.2d at 882.

Baxter argues that the entirety of the '131 Patent, including its Title, Abstract, Background,

and Detailed Description,[17] make clear that the inventions relate *only* to hemodialysis machines or apparatuses and that to find otherwise would be improperly reading the claims as calling for a "medical apparatus." Fresenius, on the other hand, contends that the preamble to the '131 Patent, which requires a hemodialysis apparatus, is not a limitation as a matter of law because a claimed apparatus must be considered only in light of what it is and not what it does. In support of its argument, Fresenius relies heavily on *In re Schrieber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (holding that a claimed popcorn-dispensing device was anticipated by a prior art oil-dispensing can even though the prior art never contemplated the intended use or function that was recited in the body of the claim) and *In re Hack*, 245 F.2d 246, 248 (C.C.P.A. 1957) (recognizing the "principle that the grant of a patent on a . . . machine cannot be predicated on a new use of that machine").

Fresenius' reliance on *Schrieber* and *Hack* is misplaced, however. Contrary to Fresenius' assertion, the Federal Circuit did not hold, in *Schrieber*, that language pertaining to a patent's function may never be given patentable weight. Instead, the Federal Circuit found that, based on the facts of that particular case, the functional limitations of the asserted claims were inherent in the prior art reference. *Schrieber*, 128 F.3d at 1478. Further, *Hack*

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[17] The Title of the '131 Patent is "Method and Apparatus for Kidney Dialysis." The Abstract states that "[a] number of improvements relating to methods and apparatuses for kidney dialysis are disclosed." The Field of the Invention provides that "[t]he present invention relates to improvements in kidney dialysis machines." See 131:1:13-14.

merely stands for the general proposition that one cannot patent an old product based on a newly discovered use. *Hack*, 245 F.2d at 248.

Notwithstanding the holdings of *Schrieber* and *Hack*, the Federal Circuit has repeatedly instructed that the preamble *must* be construed as a limitation of the claim when it provides antecedent basis for terms in the body or recites essential structure for the invention. "When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) (citing *Eaton Corp. v. Rockwell Int. Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003)). Here, the term "hemodialysis apparatus" appears in the body of the claim and the only possible antecedent basis for that term is from the preamble. Thus, Fresenius has not shown that the patentee is using the preamble "only to state a purpose or intended use for the invention" and has otherwise defined "a structurally complete invention in the claim body." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997); *Kropa v. Robie*, 187 F.2d 150, 152 (C.C.P.A. 1951).

Additionally, the Federal Circuit has held that language of essential structure and purpose in a preamble provides "positive limitations to the invention claimed." *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1256-57 (Fed. Cir. 1998) ("To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality. The invention is restricted to those fibers that work as waveguides as defined in the specification."); *Trintec Indus.*, 295 F.3d at 1296 ("[t]he difference between a printer and a photocopier

may be minimal and obvious to those of skill in the art. Nevertheless, obviousness is not inherent anticipation."); *Poly America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309-10 (Fed. Cir. 2004).

Here, the terms "hemodialysis" and "dialysate" not only appear in the preamble, but also in the body of the claim. In fact, the words "dialyzer," "hemodialyzer" and "dialysate" are all present in the claim. Moreover, the word "dialysate" is found independently or tied to other structural elements *seven* times in claim 1 of the '131 Patent. Additionally, claim 1 specifically requires the structural element of "a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the *hemodialysis apparatus*." *See* 131:1-3, 13-16 (emphasis added). Because the Federal Circuit has expressly held that the functional language in the body of a claim cannot be ignored, the presence of these specific terms in the body of the claim is a strong reason why patentable weight must be given to the terms. *See Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 689 (Fed. Cir. 1990); *see also Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810-811 (Fed. Cir. 2002) ("[b]y virtue of its [the intended use] inclusion in the body of Claim 25, this phrase limits Claim 25"). In fact, if this Court were to adopt Fresenius' position, the Court would be reading the words "hemodialyzer" and "dialysate" out of the claim. This the Court cannot do. It is well established that "all claim terms are presumed to have meaning." *In-*

nova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1119 (Fed. Cir. 2004).[18]

Since the asserted claims of the '131 Patent require a hemodialysis apparatus, and since it is beyond dispute that the Sarns 9000 is a heart-lung machine and *not* a "hemodialysis apparatus," Baxter is entitled to summary judgment on this basis alone. However, the Court is also persuaded by the additional reasons Baxter has set forth as to why the '131 Patent is not anticipated by the Sarns 9000.

2. "Dialysate-Delivery System" Limitation

For example, Baxter has persuasively shown that the Sarns 9000 does not meet the claim limitation requiring a "dialysate-delivery system."[19] According to Fresenius' own expert, Mr. Causey, a "dialysate-delivery system" includes, at a minimum, a pump, a dialysate reservoir, a membrane system, and a control system, such as a microcontroller or microprocessor. Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 48:10-49:24). In light of this testimony, Fresenius' argument that element (a) of claim 1 merely requires "a pump that can circulate

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[18] While Fresenius also relies heavily upon *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000), this case does not support Fresenius' theory. The term at issue in *IMS* ("control apparatus") was not found in the body of the claim – it *only* appeared in the preamble. *IMS*, 206 F.3d at 1427-28.

[19] Part (a) of claim 1 recites "a dialysate-delivery system for supplying dialysate to a hemodialyzer." The dialysate-delivery system may comprise either "a dialysate-preparation unit," "a dialysate-circulation unit," or "a dialysate-monitoring unit."

dialysate" is unavailing. Further, even assuming, *arguendo,* that claim 1 of the '131 Patent merely requires a pump, then at most there is a dispute of fact as to whether the roller pumps on the Sarns 9000 are accurate enough to perform any hemodialysis functions. *See* Bruner Decl. at ¶¶ 19-27 (opining that the pumps on the Sarns 9000 are not capable of performing hemodialysis functions); *see* Riley Decl. at ¶ 6 (stating that "[a]ny of the five roller pumps on the Sarns 9000 is capable of delivering dialysate to a hemodialyzer"). As such, Fresenius still would not be entitled to summary judgment in its favor on this defense.

3. The "Time-Variable Profile" Limitation

Additionally, Baxter has shown that the Pulsatile screen described in the Sarns Manual does not meet the "time-variable profile" claim limitation. Fresenius argues that the graph depicted on the Pulsatile screen is a "time-variable profile" with a "time-based abscissa" because it is a graphical depiction of the relationship between pump speed and time. McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. J (Sarns Manual at F299054) ("[T]he x axis represents time while the y axis represents speed."). In support of this argument, Fresenius relies on the fact that, in the June 2005 office action, the Patent Office concluded that the Sarns System meets the "time-variable profile" and "time-based abscissa" limitations. However, as this Court has previously noted, and as set forth in greater detail with respect to the obviousness analysis, a patent examiner's findings alone are insufficient to merit summary judgment on the issue of validity. *S3, Inc.*, 1999 U.S. Dist. LEXIS

23218 at *86-87 (N.D. Cal. 1999) (Armstrong, J.). Rather, a district court must review a patent's validity independently of the patent examiner. *Id.*; *see also Quad Env. Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 876 (Fed. Cir. 1991). Accordingly, this Court must make its own determination as to whether Fresenius has met its burden, in these proceedings, of producing clear and convincing evidence that the Sarns 9000 meets the "time-variable profile" limitation.

Fresenius has not met this burden, largely because the current position it has taken with respect to the Pulsatile screen flatly contradicts the position it took with respect to infringement. Specifically, when arguing that certain screens of Fresenius' 2008K machine did not infringe the '131 Patent, Fresenius stated:

> Baxter accuses three alleged parameters associated with Kt/V of being 'the operational parameter' called for in element (b) of Claim 1 of the '131 patent. . . . ***None of these alleged parameters, however, is varied over the course of the treatment***. Rather, each one is entered, if at all, as a single number, which remains constant during the treatment. ***Because these three alleged parameters do not vary over time, no 'time variable profile' of them is ever displayed***.

See Fresenius Opp. to Baxter Mot. for Partial SJ of Literal Infringement at 18:8-16 (emphasis added).

This argument was based on the opinion testimony of Fresenius' expert, Mr. Crnkovich, who stated:

> None of these alleged parameters, however, is varied ***over the course of the treatment***. Rather, each one is entered, if at all, as a single number, which remains constant during the treatment. Because these three alleged parameters do not vary over time, no "time-variable profile" of them is ever displayed.

Abernathy Decl. at Ex. 19 (Crnkovich Decl. at ¶ 32) (emphasis added).

Fresenius cannot contend that the "time-variable profile" limitation must be construed one way to avoid infringement and then argue for another construction of the claim limitation to invalidate the patent.[20] It has long been held that "[a] patent may not, like a 'nose of wax,' be twisted one way to avoid anticipation and another to find infringement ." *Sterner Lighting, Inc. v. Allied Elec. Supply, Inc.*, 431 F.2d 539, 544 (5th Cir.1970).[21]

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[20] Notably, the Court adopted Fresenius' position when it granted summary judgment in Fresenius' favor on the issue of whether the Kt/V screens literally infringed the '131 Patent.

[21] Further, while Fresenius now argues that the Court should not construe the patent in this manner, this construction is, in fact, consistent with the '131 Patent specification. (131:9:19:23 ("[t]he x-axis represents treatment period"); 131:9:48-54 ("Be-

Further, as Baxter points out, although the Sarns Manual does state that the "x-axis represents time," the Manual also makes clear that what is actually displayed on the x-axis is not "time" in the sense of the "course of treatment," but rather "a proportion (%) of one pump cycle." Abernathy Decl. ISO Baxter MSJ at Ex. 3 (Sarns Manual at F299055). Additionally, it is undisputed that each component of pulsatile flow (Rate, Width and Base) is entered as a single number and remains constant during the entire procedure. *Id.* In fact, several of Fresenius' witnesses testified to the fact that the relationship between the maximum and minimum pumping phases remains constant and can only be changed manually by the operator.

For example, when explaining the static nature of the pulsatile waveform, Mr. Griewski stated:

> Q. [Y]ou, I think, testified earlier that referring to the pulsatile waveform, it would not show more than two cycles of the pulsatile waveform because it would show more repetition of the same thing. Do you recall that?
>
> A. Yes.
>
> Q. What did you mean by that?
>
> A. Well, to hopefully -- hopefully clarify it, what it means is that when the user inputs these values, then until the user changes them again, that it would be essentially duplicate

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fore permitting the user to program the sodium profile . . . [i]f the treatment time was not earlier programmed, the machine also solicits this data"); 131:18:11-20 ("treatment time and target UF volume have been entered and a machine-calculated UF rate is used")).

> information. So another way maybe to say that – say this is if I went to the screen and I put, you know, zero at this side for the number of cycles, then you would see one of those kind of like dot, dot, dot, you know, and then another. So it -- it would be sort of silly on the screen to -- you know, to represent any more than -- than the two -- than the two cycles. The two-cycle graphical image is to allow the user to better see the relationship between the peaks and the valleys.
>
> Q. If I understand your testimony correctly, the waveform is fixed?
>
> A. It's fixed until the user alters it.
>
> Q. Right. And it's fixed and cannot vary unless the user changes it during treatment.
>
> A. Yes, sir.

Abernathy Decl. at Ex. 4 (Griewski Depo. at 240-41).

Additionally, Fresenius' expert, Mr. Causey, testified:

> Q. Is it your understanding that the relationship between the maximum and minimum pumping phases remains constant throughout treatment, unless the operator changes it?
>
> A. I believe that to be the case, but I would have to go back and review the manual, but I can't recall it automatically changing.
>
> . . .

> Q. Once that phenomenon occurs, the pulsatile flow does not change across treatment time?
>
> A. I believe it's repeated and - and stable at that - at that blood volume per time until changed by the operator, and I believe that morphology is constant until its changed by the operator.

Abernathy Decl. at Ex. 10 (Causey Depo. at 165-66, 173).

Since it is undisputed that the square waveform represents two beats of a human heart, Baxter has shown that the profile is not a "time-based profile" because the profile displayed on the Pulsatile screen is fixed and spans only a few seconds[22] rather than over the course of the treatment.

Thus, based on Fresenius' own admissions, the Sarns 9000 does not meet the "time-variable profile" claim limitation.

4. Inherent Anticipation

Finally, Baxter has shown that Fresenius' "inherent anticipation" argument is without merit. Fresenius argues that, even if the phrase "for supplying dialysate to a hemodialyzer" in claim 1 is given patentable significance, the asserted claims of the '131 patent are inherently anticipated. A prior art reference may anticipate "without disclosing a feature of

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[22] Sixty beats per minute translates into one beat per second, meaning the waveform displayed would span less than two seconds, a fact Fresenius' expert Mr. Causey conceded. Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 163).

the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *Cont'l Can Co.*, 948 F.2d at 1268.

Fresenius' inherent anticipation argument is premised on its contention that it was common knowledge to those of ordinary skill in the art – at least as early as 1979 – that during cardiac surgery, toxins and fluids could be removed by adding a dialyzer and dialysate to the extracorporeal circuit of a perfusion system used during cardiac bypass surgery in the same way these items would have been added to the extracorporeal circuit of a hemodialysis machine. To support its inherent anticipation argument, Fresenius relies on four articles (referred to herein as "the Perfusion Articles"), which purportedly describe performing hemodialysis during open-heart surgery: (1) Soffer et al., *Interoperative Hemodialysis During Cardiopulmonary Bypass In Chronic Renal Failure*, J. Thoracic and Cardiovascular Surgery, Vol. 77 (1979); (2) Hakim et al., *Haemodialysis and Hemofiltration on Cardiopulmonary Bypass*, Thorax, Vol. 40 (Feb. 1985); (3) Wiggins et al., *Simultaneous Cardiopulmonary Bypass and Dialysis*, Journal of Extra-Corporeal Technology, Vol. 17, No. 3 (Fall 1985); and (4) Murkin et al., *Hemodialysis During Cardiobypass*, Anesthesia and Analgesia, Vol. 66, No. 9 (Sept. 1987).[23] *See* Abernathy Decl. at Exs. 13-

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[23] Fresenius also relies on a fifth perfusion reference entitled: *Hemofiltration, Dialysis, and Blood Salvage Techniques During Cardiopulmonary Bypass*, printed in Cardiopulmonary Bypass Procedures: Principles and Practice (1993). *See* Abernathy Decl. ISO Baxter MSJ at Ex. 17. However, since this article was pub-

16. According to Fresenius' main expert witness, the Perfusion Articles establish that "the Sarns System could be used to perform kidney dialysis during cardiac bypass procedures by adding a dialyzer to the extracorporeal circuit of the perfusion system." *See* Abernathy Decl. ISO Baxter MSJ at Ex. 18 (Causey Report at 107).

Fresenius' argument necessarily fails, however, because none of the Perfusion Articles even mentions the Sarns 9000. *Continental Can Co.*, 948 F.2d at 1268 (holding that when resorting to "extrinsic evidence" to fill a gap in a reference, "such evidence must make clear that the missing descriptive matter is necessarily present"). While it is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference, "[s]uch factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Because there is no mention of the Sarns 9000 in the articles, Baxter is correct that the Perfusion articles are outside of the "four corners" of the Sarns Manual and are not clear and convincing evidence of anticipation. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

In fact, Fresenius' own witness has admitted that he is not aware of any publications showing that

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lished *after* the priority date for the '131 Patent, it has not been considered by the Court.

the Sarns 9000 has ever been used to perform hemodialysis:

> Q. Are you aware of any published literature describing the use of the Sarns 9000 to perform hemodialysis?
> A. No, I'm not.

Abernathy Del. at Ex. 9 (Riley Depo. at 200:13-21); *see also id.* at Ex. 10 (Causey Depo. at 241:8-16).

Moreover, although the Perfusion Articles generally discuss hemodialysis performed on patients during open-heart procedures, they do ***not*** specifically disclose using a heart-lung machine for that purpose. *See* Abernathy Decl. ISO Baxter MSJ at Exs. 13-16. In fact, each of the articles makes clear that a separate pump, hemodialysis machine and/or vacuum source is always required. *Id.*

Thus, Fresenius has not established by clear and convincing evidence that the Perfusion articles even suggest that heart-lung machines could be used during open-heart surgery to perform hemodialysis, and there is no evidence that the Sarns 9000 was used this manner. This precludes a finding of "inherent" anticipation. Even if the Sarns 9000 could have been used for hemodialysis, the law is clear that inherent anticipation "may not be established by probabilities or possibilities." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

Accordingly, based on all of the aforementioned reasons, the Court hereby GRANTS Baxter's Motion for Summary Judgment with respect to the anticipation affirmative defense and DENIES Fre-

senius' Motion for Summary Judgment on anticipation.

B. Obviousness

In its Motion for Summary Judgment, Fresenius also alleges that it has established a strong case of obviousness due to its contention that the Sarns Manual, when combined with Kerns, Rubalcaba, and Lichtenstein, renders the asserted claims of the '131 and '434 Patents obvious.[24] Baxter, on the other hand, has not moved for summary judgment on this issue and argues that there are numerous disputed material facts precluding summary judgment, including: (1) whether the Sarns Manual and the cardiopulmonary bypass related materials are "analogous art"; (2) whether one skilled in the art[25] would have any "motivation to combine" Lichtenstein with Kerns, Rubalcaba or the Sarns Manual; (3) whether

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[24] Because the '434 and '131 Patents have a priority date of April 19, 1991, their validity with respect to other patents, printed publications, and public use within the United States is judged as of one year before the priority date, or April 19, 1990. *See* 35 U.S.C. § 102(b). Kerns and Rubalcaba issued on July 12, 1988 and February 6, 1990, respectively. Lichtenstein issued February 1, 1983. There is no dispute that Kerns, Rubalcaba, and Lichtenstein have priority to the '434 and '131 Patents. There is also no dispute that the Sarns 9000 was offered for sale and sold no later than 1988.

[25] The parties agree that the level of ordinary skill in the art is an engineer, such as a bioengineer electrical engineer, with a Bachelor of Science degree or equivalent experience, having at least three years of experience designing medical instruments and access to skilled medical personnel familiar with hemodialysis.

Lichtenstein teaches away from a user entering operational parameters, or teaches any control at all by the user; and (4) whether the secondary considerations overcome any showing of obviousness.[26]

The Court finds that Baxter is correct that the disputed facts necessitate the denial of Fresenius' summary judgment motion. The relevant arguments are summarized below.

1. Whether the Sarns Manual is Analogous Art

An obviousness analysis is based on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of nonobviousness, such as commercial success, copying, or long felt but unresolved need in the art. *Graham*, 383 U.S. at 17-18. As such, the first step in the obviousness analysis is determining whether a patent or publication is in the prior art under 35 U.S.C. § 103.[27] "Although § 103 does not, by its terms, define

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[26] The Court notes that, with respect to the secondary considerations factor, Baxter argues that the fact that Fresenius has patented touch screen technology supports a finding that the '131 Patent and the '434 Patent are nonobvious. However, as Fresenius points out, this is not a relevant *Graham* factor and merely confuses the issue by referring to patents that are not before the Court. As such, this argument has not been considered.

[27] Patent claims are invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

the 'art to which [the] subject matter [sought to be patented] pertains,' this determination is frequently couched in terms of whether the art is analogous or not, *i.e.*, whether the art is 'too remote to be treated as prior art.'" *In re Clay*, 966 F.2d 656, 658-659 (Fed. Cir. 1992). Whether something legally within the prior art is "analogous" is a question of fact. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 n. 9 (Fed. Cir. 1987). "Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Here, the parties dispute whether the Sarns Manual, and other cardiopulmonary bypass-related materials, are "analogous art." In support of its assertion that the prior art references are "analogous," Fresenius argues that cardiopulmonary bypass materials are analogous because the applicable field of endeavor is "multi-parameter medical machines." To prove this contention, Fresenius relies on the expert report of Mr. Causey and the findings of the PTO office.[28] *See* March 28, 2006 McClenahan Decl. at Ex.

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skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

[28] Fresenius also asserts that the structure of the Sarns 9000 is so similar to the claimed hemodialysis machine that the Court may conclude that cardiopulmonary bypass machines are "unquestionably analogous art for the purposes of the obviousness analysis." Fresenius' support for this proposition, however, is the expert report of Mr. Riley, who is only being admitted as a "teaching" expert to provide general background information on

J. In fact, Fresenius specifically asserts "the Court need only look to what the Patent Office has already done to see that Lichtenstein and the Sarns System are both analogous prior art." Fresenius MSJ I at 16:7-14 (stating also that "[i]f the Examiner [in the June 2005 Office Action] did not believe that the Sarns Manual is analogous prior art, he would not have relied on it."). Baxter, however, argues that Fresenius has too broadly defined the field of endeavor and that the pertinent field relates only to hemodialysis, not all medical machines. To support its position, Baxter points to the specifications of the '434 and '131 Patents, which explicitly define the "field of endeavor" as "hemodialysis." Baxter also notes that the Title and Abstract of both Patents refer exclusively to hemodialysis machines. 434:1:5-6, 131:1:13-14. Additionally, Baxter notes that every claim in the '434 and '131 Patents requires either a hemodialysis machine or a hemodialysis apparatus. Due to these conflicting factual issues, the Court cannot conclude that Fresenius has carried its burden of establishing that cardiopulmonary bypass references are analogous art as a matter of law.

Further, Baxter has also produced evidence that arguably casts doubt on Fresenius' expert's contention that the problem the inventors were trying to solve was "to select and design an appropriate user interface for a medical machine." *See* March 28, 2006

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the Sarns 9000 and hemodialysis. As Fresenius concedes in its opposition to Baxter's Motion to Bar the Expert Testimony of Riley, Mr. Riley has not read the patents-in-suit and therefore is not being offered as an expert on the validity of the patents-insuit. As such, the Court has not considered this argument as clear and convincing proof that the Sarns 9000 is analogous prior art.

McClenahan Decl. at Ex. J (Causey Expert Report at ¶ 117). For example, Baxter has elicited admissions from the design team of the Fresenius 2008K that they have no recollection of ever having read or reviewed any cardiopulmonary bypass references prior to having designed the machine. Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 25. Additionally, neither the Fresenius engineers nor the inventors of the patents-in-suit had even heard of the Sarns 9000 until after this litigation began. Further, Baxter has produced testimony from its expert, Dr. Bruner, who has stated that the problems facing designers of hemodialysis machines differed significantly from those faced by engineers in the field of cardiopulmonary bypass procedures. Bruner Decl. at ¶¶ 11-18, 28. As a result of these disputed facts, the Court concludes that the first criterion of the obviousness test has not been met as a matter of law because a reasonable juror could find that the prior art references and the claimed subject matter are either not in the same field of endeavor or not pertinent to the particular problem the inventors were trying to solve. *See, e.g., Wang Labs, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864-865 (Fed. Cir. 1993).

2. Motivation and the Teachings of Lichtenstein

Another issue that is in dispute is whether one skilled in the art would have any "motivation to combine" Lichtenstein with the other prior art references. "In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have lead a person of ordinary skill in the art to select the references and combine them in a way

that would produce the claimed invention." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). Motivation to combine may be found in the prior art references themselves, the knowledge of those skilled in the art, or in the nature of the problem itself. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 1996). The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

Fresenius contends that it is entitled to summary judgment because the Patent Board "has already determined that one of ordinary skill in the art would have been motivated to combine a touch screen user interface such as that disclosed in Kerns, Rubalcaba, or the Sarns Manual with a computer-controlled hemodialysis machine such as that disclosed in Lichtenstein." Indeed, in the August 2003 Opinion, the Board noted that:

> From a number perspectives, the use of a touch screen input/output device for computer control purposes in both types of modular apparatuses used for medical purposes in similar manner would have been readily suggested to one of ordinary skill in the art by the very nature of the apparatuses and the known attributes of a touch screen input/output device user interface with respect to such apparatuses[.]

McClenahan Decl. ISO Fresenius MSJ at Ex. 1.

In the June 2005 Office Action, the examiner also noted that there would have been a motivation to combine a touch screen user interface with a hemodialysis machine. In fact, he stated:

> It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the dialysis procedure as disclosed in the CMOS Manual to include utilizing a touch screen for entry of rates, volumes and profiles, as taught by the Sarns Manual . .

McClenahan Decl. at Ex. 2.

The PTO's findings certainly support Fresenius' case. However, as this Court previously noted, a patent examiner's findings alone are insufficient to merit summary judgment in favor of the accused infringer on the issue of obviousness. *S3, Inc.*, 1999 U.S. Dist. LEXIS 23218 at *86-87. This is especially true in light of the fact that a PTO examiner is only required to provide evidence which "as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a prima facie case of obviousness) is more probable than not." MPEP § 2142 (emphasis added). Thus, before granting summary judgment, a district court is required to review a patent's validity *independently* of the patent examiner. *Id.*; *see also Quad Env. Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 876 (Fed. Cir. 1991). An independent analysis is critical even when reexamination proceedings are ongoing with respect to the patents-in-suit. As stated by the Federal Circuit in *Quad*,

> In an infringement suit before a district court, the invalidity of a patent under 35 U.S.C. § 103 must be decided on the basis of prior art adduced in the proceeding before the court. The issue cannot be decided merely by accepting or rejecting the adequacy of the positions taken by the patentee in order to obtain a Certificate of Reexamination for the patent. . . . The courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner.

Id. at 876 (internal citations omitted); *see also Greenwood v. Hattori Seiko Co., Ltd.*, 900 F.2d 238 (Fed. Cir. 1990) (reversing summary judgment because district court relied solely on examiner's decision to find patent invalid).

Accordingly, before Fresenius can prevail on its defense, Fresenius must offer its own citations to, and analysis of, specific prior art. *Id.* Because Fresenius relies solely on the aforementioned PTO proceedings, and has not cited to any testimony from its expert witnesses, evidence obtained through the three-and-a-half years of discovery in this case, or admissions from Baxter witnesses, the Court concludes that Fresenius has not sufficiently established, through clear and convincing evidence, that it is entitled to judgment as a matter of law.

Further, with respect to the issue of "motivation," Baxter has shown that there are disputed ma-

terial issues that must be resolved before a finding of obviousness can be made. For example, Baxter argues that, despite the PTO's findings, a person of ordinary skill would never be motivated to combine a touch screen to Lichtenstein for the entering of hemodialysis parameters because Lichtenstein teaches that the operator was never going to be entering parameters into the Lichtenstein machine. In support of this argument, Baxter relies on testimony from its expert, Richard F. Ferraro.[29] *See* Ferraro Decl. at ¶¶ 8, 12-16, 19-20. Mr. Ferraro states that:

> I find no compelling reason, outside of using the patents-in-suit as a blueprint, for adding a touch screen to the medical instrument disclosed in the Lichtenstein '983 Patent. I do, however find there are at least two compelling reasons why not to add a touch screen: (a) there would be no useful function for the touch screen; and (b) Lichtenstein overcomes the problems with the prior art by not relying upon the operator for entering parameters.

Id. at ¶ 15.

The parties are also in dispute as to whether or not the Lichtenstein patent "teaches away" from a user entering operational parameters. "What a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact." *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993). A refer-

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[29] Mr. Ferraro has a Master's Degree in Electrical Engineering and has been an electrical engineer for over thirty years. Ferraro Decl. at ¶ 3.

ence "teaches away" when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Similarly, "a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc,* 192 F.3d 1353, 1360 (Fed. Cir. 1999); *see also In re Haruna*, 249 F.3d 1327, 1335-36 (Fed. Cir. 2001). As a "useful general rule," references that teach away cannot serve to create a prima facie case of obviousness. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001).

According to Mr. Ferraro, there is no disclosure in the Lichtenstein patent where an operator inputs hemodialysis parameters through a user interface – as the asserted claims of the '434 and '131 Patents require. Ferraro Decl. at ¶¶ 12-42. To the contrary, Mr. Ferraro contends that Lichtenstein discloses how the microcomputer automatically, under computer program control, operates the machine. *Id.* at ¶¶ 23-27, 39. Mr. Ferraro also asserts that Lichtenstein unmistakably claims to improve on prior art having an "attendant" enter parameters. *Id.* at ¶¶ 24-27; *see also* Abernathy Decl. ISO Opp. to Fresenius MSJ at Ex. 8 (983:1:31-43).[30] Additionally, Baxter points out that, when asked about the teaching of "manual control" in Lichtenstein, Fresenius'

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[30] While Fresenius attempts to dismiss Mr. Ferraro's testimony as "conclusory," Mr. Ferraro actually cites quite extensively to the Lichtenstein patent in support of each of his opinions.

own witness, Mr. Causey could only identify one instance where the attendant was instructed by the computer to "shut valves." Abernathy Decl. at Ex. 3 (Causey Depo. at 217-219). Despite his deposition testimony, however, it appears that Mr. Causey disputes Baxter's contention that Lichtenstein teaches away from the claimed invention. Again, this dispute regarding the "teachings" of Lichtenstein makes summary judgment inappropriate.

3. Secondary Considerations

Further, although Fresenius instructs the Court in its Motion that the Court need not evaluate whether any secondary considerations negate a finding of obviousness, such a quick dismissal of one of the *Graham* factors is contrary to law.[31] *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387 (Fed. Cir. 1988) ("The commercial response to an invention is significant to determinations of obviousness, and is entitled to fair weight"). The Federal Circuit has often noted that secondary considerations can be the "most probative and determinative [evidence] of the ultimate conclusion of obviousness or nonobviousness." *See, e.g., Pro Mold v. Great Lakes Plastics*, 75 F.3d 1568, 1572-74 (Fed. Cir. 1996).

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[31] In fact, Fresenius' only discussion of secondary considerations in its Motion is its instruction for this Court to "look to the [August 2003] Board decision to see why Baxter's arguments regarding secondary considerations must be rejected." As discussed above, this is completely insufficient to carry its burden on summary judgment. This Court may not merely default to the Board's conclusions, particularly when the Board only considered a total of five documents pertaining to this issue.

Having considered the evidence that Baxter has offered pertaining to the "secondary considerations" factor, it is clear to the Court that this issue, too, is clouded with disputed facts. First, the parties dispute whether the System 1000[32] was commercially successful and, if so, whether the success is sufficiently related to the patented technology.

For example, Baxter argues that the System 1000 enjoyed immediate market acceptance – doubling the highest market penetration of its predecessor – and quickly became state of the art. Turner Decl. ISO Opp. to Fresenius MSJ I at ¶ 5. In support of this assertion, Baxter cites to testimony from its expert, Dr. John Turner, who explains that, between 1992 and 1993, domestic sales of the System 1000 increased by more than 146 percent. *Id.* at ¶ 7. Dr. Turner has also testified that the System 1000 generated more than $19 million in revenue by its second full year of production. *Id.* at ¶ 7. Additionally, Baxter notes that Fresenius' own internal documents reflect the fact that Althin – the owner of the patents-in-suit at the time – continued to maintain a 12 percent market share through 1999. *Id.* at ¶¶ 10-11. Baxter further argues that the marketing and sales materials stressing the benefits of the touch screen operation and the profiling options of the System 1000 show that a nexus existed between the asserted claims of the '434 and '131 Patents and the commercial success of the System 1000.[33] *Id.* at ¶ 12.

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[32] There is no dispute that Baxter's System 1000 is covered by the '434 and '131 Patents. In fact, it is incorporated by reference into the Patents.

[33] Baxter also argues that the success of Fresenius' 2008K further shows that there is a nexus between the patented technol-

Fresenius argues, however, that the System 1000 was not successful because Baxter's own data indicates that the peak unit sales of the System 1000 never reached the peak unit sales of the predecessor machine, which did not have the patented touch screen. March 28, 2006 McClenahan Decl. at Exs. B, E.[34] Fresenius further argues that Baxter has not shown that the claimed touch screen features are what drove sales of the System 1000. In fact, Fresenius points out that the relevant marketing and sales literature touted numerous features of the System

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ogy and commercial success. *See* Den Uyl Decl. at ¶ 6 (noting that Fresenius' market share increased to sixty-four percent after introduction of Fresenius 2008K); *see also* Turner Decl. at ¶¶ 18-19, 28-35 (opining that Fresenius' sales and marketing materials demonstrate a clear nexus between the patented technology and the success of the 2008K). However, Fresenius' expert, Robert Payne, disputes this conclusion and opines that the patented features did *not* drive sales of the 2008K. *See* March 28, 2006 McClenahan Decl. at Ex. D (Payne Expert Report at ¶ 46).

[34] Fresenius also argues that Baxter's expert on secondary considerations, Dr. Turner, is "hardly the right person to opine on what drove sales of the System 1000" because he "has never been involved in the design, manufacture, marketing or sale of any hemodialysis machine, let alone the System 1000." Dr. Turner holds a Ph.D. in electrical engineering and computer science from Princeton University and an MBA from the Kellogg School of Management at Northwestern University. Turner Decl. at ¶ 3. He was also a postdoctoral fellow and research associate at Stanford University. *Id.* His medical industry experience includes more than fifteen years of designing, developing, marketing, and manufacturing FDA approved medical devices. *Id.* at ¶ 4. Given Dr. Turner's credentials and experience, Fresenius' criticisms of Dr. Turner are unfounded. Similarly unfounded is Fresenius' argument that Dr. Turner's declaration should be ignored because it is "conclusory." Contrary to Fresenius' assertion, Dr. Turner's declaration is replete with citations to the specific evidence supporting his opinions.

1000, not just the touch screen and profiling options. March 28, 2006 McClenahan Decl. at Ex. D (Payne Expert Report at ¶ 35).

The parties also dispute whether Fresenius copied Baxter's patented technology.[35] For example, Fresenius' witness, Mr. Crnkovich,[36] has affirmatively stated that Fresenius did *not* copy the System 1000. Crnkovich Decl. at ¶¶ 7-10. However, Baxter alleges that Fresenius' witnesses admitted using the System 1000 and its manual to develop its own 2008K machine:

> Q. In developing the 2008K, did you have information relating to the Althin System 1000?
> A. Yes.
> Q. What information did you have?
> A. We had an operator's manual.
> Q. Did you have anything else?
> A. I think we had a machine also.

Ex. 19 (Crnkovich Depo. at 29:4-10.

Baxter also asserts that Fresenius' research and development documents confirm that it borrowed heavily from the System 1000. For example, during the

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[35] The Federal Circuit has noted that "wholesale copying" provides "compelling evidence of nonobviousness." *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1285-86 (Fed. Cir. 2000).

[36] Mr. Crnkovich is the senior R&D Manager for hemodialysis equipment development at Fresenius. Crnkovich Decl. at ¶ 1.

early stages of the development process, Fresenius' 2008K Project Manager, Martin Crnkovich, stated: "We are working at developing a touch screen that performs and looks better than the Althin machine." Abernathy Decl. ISO Opp. to Fresenius MSJ I at Ex. 20.

Additionally, Baxter contends that Fresenius' confidential strategic documents reveal that Fresenius intentionally adopted a touch screen user interface in order to protect its market position:

> Our competitors are introducing new machines with a new improved user interface. Each of the machines being introduced has a high-resolution color LCD/CRT display with a touch screen interface. To maintain our competitive edge, we must upgrade the control unit on the 2008H to one that is state of the art.

Id. (emphasis added).

Further, Baxter's expert on commercial success, Dr. John Turner, has also opined that Fresenius positioned the 2008K to compete directly against the patented touch screen features of the Althin System 1000. Turner Decl. at ¶¶ 20-21. When this evidence is compared to Mr. Crnkovich's testimony denying that Fresenius copied the System 1000, it is clear that this factual issue is in dispute.

There is also a dispute as to whether there was any skepticism as to the claimed invention's feasibility. Testimony expressing skepticism about an invention's feasibility is an important secondary fac-

tor. *The Gillette Company v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725-26 (Fed. Cir. 1990). Baxter contends that testimony from Fresenius' CEO, Dr. Ben Lipps, and R&D Manager, Mr. Crnkovich, support a finding that the marketplace was skeptical about the feasibility of Baxter's patented technology. For example, Dr. Lipps has testified that, in the mid-to-late 1980s, he did not consider touch screens reliable enough to use in the hemodialysis field:

> A. Well, just one of the features of a dialysis machine is it has to be reliable and it has to provide basically the latest therapy, so I tried to get the guys to focus on the sodium variation and the therapy and the reliability. And touch screens at that time were highly unreliable, and they weren't necessary at all as an interface. We sold most of the market using just buttons, okay, because the machine was good, it had great quality. So I kind of brought them back to the reality that it was not economical and not reliable at that point to use a touch screen.

Abernathy Decl. ISO Opp. to Fresenius MSJ at Ex. 24 (Lipps Depo. at 38).

Dr. Lipps also explained that the environment that a hemodialysis machine operated in precluded the use of a touch screen:

> Q. When you say "reliability wasn't there," describe what you mean.

> A. ell, there were two issues. One of them was the length of mean time between failure between - before having a film failure from just operating. And the other one was the environment they operated in where they clean the machines on a regular basis, sometimes between treatments and sometimes once a day, the data did not indicate that these touch screens would hold up at that time, and I was very leery of them.
>
> . . .
>
> Q. And the data you're referring to is data as to use of a touch screen?
>
> A. Whoever manufactures, yeah, they were used in a number of devices and people were - but the use of our device was so heavy in terms of, you know, 20 hours a day, six days a week, that it was just not the right decision at that point from my standpoint.

Id. at Ex. 24 (Lipps Depo. at 65-66).[37]

Fresenius argues, however, that the testimony cited by Baxter does not bear on the issue of technological incompatibility, which is relevant to obviousness, but addresses only whether Fresenius had business concerns, which is not relevant. *See In re Farrenkopf*, 713 F.2d 714, 718 (Fed. Cir. 1983) ("That a given combination would not be made by busi-

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[37] Mr. Crnkovich echoed this sentiment by stating that he did not "have a good experience" with touch screens in the 1980's. Abernathy Decl. at Ex. 19 (Crnkovich Depo. at 10:8-11:10, 13:20-14:5).

nessmen for economic reasons does not mean that persons skilled in the art would not make the combination because of some technological incompatibility. Only the latter fact would be relevant.") In support of this assertion, Fresenius cites to testimony from its own witness, Dr. Lipps, who has stated that Fresenius' decision not to implement a touch screen in the 1980s was for business reasons. Lipps Decl. at ¶ 7.

Again, however, Fresenius' argument does not support a finding of summary judgment, it merely supports the conclusion that there are disputed issues of fact that cannot be resolved at summary judgment. *Monarch Knitting Machinery Corp. v. Sulzer Morat Gmbh*, 139 F.3d. 877, 885-86 (Fed. Cir. 1998); *Scripps Clinic*, 927 F.2d at 1578 (noting that "[i]n patent cases, questions by affidavit are disfavored.").

Accordingly, due to the numerous disputed factual issues – including issues that bear directly on Fresenius' prima facie case of obviousness – the Court hereby DENIES Fresenius' Motion for Summary Judgment.

C. Fresenius' "Touch Screen" Best Mode Defense

Next, in its Motion for Partial Summary Judgment of Validity, Baxter has moved for summary judgment on Fresenius' "touch screen" best mode defense. Additionally, Fresenius has separately moved for summary judgment on this issue. Fresenius' "touch screen" best mode defense is premised on its belief that the "touch screen claims" of the patents-in-suit are invalid because they violate the best

mode requirement of 35 U.S.C. §112 in that they disclose the use of a "touch screen," but not a "resistive" touch screen.

With respect to this affirmative defense, Fresenius bears the burden of proving, by clear and convincing evidence, that, at the time of filing the patent applications, the inventors of the patents-in-suit considered resistive touch screens to be the best mode for practicing the invention claimed in the patents and nevertheless concealed that fact from the public. *High Street Concrete Structures, Inc.*, 377 F.3d at 1382. Fresenius must also show that the patent specifications are inadequate to enable one of ordinary skill in the art to practice the best mode. *Bayer AG*, 301 F.3d at 1320.[38]

In support of its Motion, Fresenius relies solely on the following evidence: (1) that one of the twelve inventors, Mr. Harley Johnson, preferred resistive touch screens;[39] and (2) that the Elographics

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[38] With respect to this affirmative defense, Fresenius bears a heavy burden. In fact, in 2002, the Federal Circuit noted that it had held claims invalid for failure to satisfy the best mode requirement on only *seven* prior occasions. *See Bayer AG*, 301 at 1316.

[39] Specifically, Fresenius relies on the following deposition testimony elicited from Mr. Johnson:

> Q: In the SATRN system, . . . did it use a resistive touch screen?
>
> A: Yes.
>
> Q: Why did it use a resistive touch screen?
>
> A: Well, we had experimented with capacitive and [] peizoresistive and the straight resistive screens and found that [] the resistive touch screen was a better performer for [] this product."

part numbers set forth in the patent specification relating to the touch screen and the touch screen controller are wrong. Having reviewed all of the evidence produced by both parties in their crossmotions, the Court concludes that there is no dispute of material fact and that Fresenius has failed to meet its burden of proof on this defense.

Neither party disputes that the part numbers disclosed in the patents are inaccurate. However, it is also undisputed that the patents disclose Elographics as the preferred touch screen supplier[40] and that the part numbers do generally relate to Elographics' AccuTouch resistive touch screen product line. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 21 (Phares Depo. at 72:13-75:3). In fact, ninety-five percent of the touch screens sold by Elographics during the relevant period were resistive touch screens. *Id.* (Phares Depo. at 23:19-23). Further, Elographics' product brochures touted the company's "Proven Resistive Technology" for touch screens used in "Medical Instrumentation" and Elographics regularly worked with companies to choose the right screen for their devices. Abernathy Decl. ISO Baxter MSJ at Ex. 20 (Phares Report at ¶ 37); *see also id.* at Ex. 23 (Elographics Product Brochures). In addition to these facts pertaining to Elographics, it is undisputed that resistive touch screens were well known by those skilled in the art at the time the patents issued. In fact, Fresenius' own expert witness, Mr. Causey, ad-

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Zheng Decl. ISO Opp. to Baxter Mot. to Strike Defenses at Ex. O (Johnson Depo. at 70-71).

[40] For example, the '434 Patent discloses that "Touch screens are known in the art and are commercially available from a number of sources, including Elographics West of San Diego, Calif." *See* 434:8-21, 434:31:38-46.

mitted to this. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 227).[41] Finally, and significantly, there is absolutely no evidence that any of the inventors intended to conceal the use of resistive touch screens from the public.[42] Again, Fresenius' witness, Mr. Causey, conceded this fact as well. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 234:19-25) ("I'm not aware of an intent to conceal.").

Thus, the undisputed evidence does *not* clearly and convincingly establish that a person of ordinary skill in the art would be unable to practice the best mode based on the patent specifications. Further, the Federal Circuit has explicitly held that the best mode requirement is "not violated by unintentional omission of information that would be readily known to persons in the field of the invention." *High Concrete, Inc.*, 377 F.3d at 1383. Accordingly, the Court hereby GRANTS summary judgment in Baxter's favor on Fresenius' touch screen claims best mode defense and DENIES Fresenius' Motion for Summary Judgment on this defense.

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41 Q: It was widely known in the field, based on your experience, that resistive touch screens could be used on medical devices, right?

A: Yes. Yes, absolutely.

Q: That's your experience?

A: Yes, my personal experience.

See Abernathy Decl. ISO Baxter MSJ at Ex. 10 (Causey Depo. at 227:16-21).

42 In fact, as to eleven of the twelve named inventors, Fresenius has produced no evidence whatsoever.

D. "Extensive Innovation" Enablement and Best Mode Defense

Alternatively, in its Motion for Summary Judgment, Fresenius alleges that the touch screen claims are invalid because they violate *both* the enablement and the best mode requirements of 35 U.S.C. §112 due to the fact that the patents-in-suit do not disclose "extensive innovations."[43] As previously stated, because the grant of a patent by the PTO carries with it the presumption of validity, invalidity for lack of enablement and violation of the best mode requirement must be shown by clear and convincing evidence.

Again, with respect to these affirmative defenses, Fresenius has not met its burden of proof. In fact, Baxter has persuasively shown that it is entitled to summary judgment in its favor because there is an absence of *any* evidence – much less the clear and convincing kind – supporting these affirmative defenses. *Celotex*, 477 U.S. at 325. For example, Fresenius has not set forth any evidence showing that a person of ordinary skill in the art would be unable to practice the claimed inventions based on the actual disclosures in the specifications, including the patents' appendices, which are in excess of 400 pages. Instead, Fresenius' expert, Mr. Phares, has admitted that it would *not* have required undue experimentation to implement a touch screen on any device claimed in the patents-in-suit. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 22 (Phares Report at ¶¶ 51-52).

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[43] These affirmative defenses also serve as the basis for Baxter's cross-Motion for Partial Summary Judgment of Validity.

Indeed, the only "evidence" that Fresenius has cited in its briefing on this issue, which is paltry, relates solely to certain statements made by Baxter's attorneys during patent prosecution and is not relevant to an enablement determination.[44] *Compare with Ajinomoto*, 228 F.3d at 1338 (noting that the district court found the patent enabling after considering extensive expert testimony on the issue). For instance, Fresenius relies on the fact that Baxter argued during prosecution of the family of patents-in-suit that its claims were patentable because providing a hemodialysis machine with a touch screen required extensive innovation in hardware and software. Specifically, Fresenius notes that, during prosecution of the '922 Application, to which the '131 patent claims priority, Baxter argued:

> Providing a hemodialysis machine with a touch screen is not the same as simply adding a different style of gauge to, or changing the arrangement of manual controls on, the front panel of the machine. Rather, providing a hemodialysis machine with a touch screen requires extensive innovation in hardware and software. Lichtenstein and Weiss are completely silent on even how to begin such an endeavor.

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[44] In fact, some of the evidence Fresenius relies on pertains to the prosecution of a separate application, Application No. 09/067,922 ("'922 Application") which involves claims not at issue here. Arguments made during the prosecution of claims that are not at issue in the instant litigation are not clear and convincing evidence relevant to Fresenius' enablement affirmative defense.

McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. Q.

Fresenius also notes that during prosecution of the '434 patent, Baxter stated:

> Contrary to the Examiner's statement in the Office Action, it would not have been obvious to a skilled artisan to substitute, for example, an analog display (as recited in claims 35-37) on a touch screen for a digital display. An analog display requires substantially different software than a digital display. A skilled artisan viewing a digital display as disclosed in Kerns et al. would neither be motivated to devise an analog display nor be provided with any indication of how to provide an analog display on a touch screen by referring to the Kerns et al. disclosure.

Id. at Ex. R.

However, as Baxter points out, these statements were made after all the asserted claims were allowed in relation to an obviousness rejection of claims of a different patent application. Further, according to Baxter, the cited remarks in the '434 Patent prosecution history have nothing to do with providing a touch screen on a hemodialysis device, but rather the motivation to display data in an analog format, rather than a digital format.[45]

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[45] Moreover, although Fresenius claims that Baxter's 30(b)(6) representative, Tom Kelly, a named inventor of the '434 and '131 patents, could not clearly answer Baxter's queries regard-

Fresenius' argument that the patents fail to disclose the software that controls the machine or the user interface is also unpersuasive. The Federal Circuit has repeatedly held that when the subject matter is a computer program that implements a claimed device, enablement is determined from the viewpoint of a skilled programmer. *See e.g., Northern Telecom*, 908 F.2d at 941. Where software constitutes part of implementing an invention, disclosure of such is satisfied by a description of the functions of the software. *Fonar Corp. v. General Elect. Co.*, 107 F.3d 1543, 1549 (Fed. Cir. 1997). Flow charts or source code listings are not a requirement for adequately disclosing the functions of software. *Fonar Corp.*, 107 F.3d at 1549; *Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 112 F.3d 1163, 1166 (Fed. Cir. 1997) (finding sufficient disclosure because the functions required for software to instruct the computer to control the machine are apparent from the specification to one of ordinary skill in the art).

Here, Baxter has cited to evidence showing that the specification provides ample details and functionality of the system required to provide a touch screen user interface for displaying and changing operational parameters of a hemodialysis machine. For example, the '434 Patent specification discloses that "[t]erminate and stay resident software for driving the interface board . . . is available from Elographics," which is the software that controls the touch screen controller and provides information to the system that the touch screen has been touched.

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ing the "innovative" hardware and software, Baxter argues that Mr. Kelly informed Fresenius that the entire host system that controls the dialysis machine and the user interface is innovative. *Id.* at Ex. S (Kelly Depo. at 92:6-7, 97:11-24).

434:13:44-46. It also describes the host control program, which provides for, *inter alia*: data input from the touch screen, data gathering from various controller sub-systems (including the blood pump, I/O, and ultrafiltration), outputting control functions to the various sub-systems, monitoring and evaluating the data, and displaying the data to the touch screen user interface. 434:13:1-17. Software flow diagrams for various software modules used to control the hemodialysis machine are also provided. *See, e.g.*, 476:237-262.

As for the software application for the user interface, the patent specification contains numerous descriptions and examples of screen layout, design, and application functionality for setting, modifying, and displaying various hemodialysis treatment parameters, including time-variable treatment parameters. *See, e.g.*, 434:8:42-11:39. Fresenius has produced no evidence that a skilled programmer, using these disclosures as a blueprint, would be unable to practice the inventions. As such, the Court GRANTS Baxter's Motion for Summary Judgment on Fresenius' enablement and best mode defenses.

CONCLUSION

IT IS HEREBY ORDERED THAT Baxter's Motion for Partial Summary Judgment of Validity [Docket No. 448] is GRANTED. Baxter is entitled to summary judgment in its favor on Fresenius' affirmative defenses of enablement and best mode, as well as judgment in its favor that the Sarns 9000 does not anticipate the asserted claims of the '131 and '434 Patent.

IT IS FURTHER ORDERED THAT Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131 [Docket No. 436] is DENIED. Fresenius' 35 U.S.C. § 103 obviousness affirmative defense shall be resolved by the trier of fact.

IT IS SO ORDERED.

Dated: 5/16/06

SAUNDRA BROWN ARMSTRONG
United States District Judge

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.,
Plaintiffs,

No. C 03-1431 SBA

ORDER

v.

BAXTER INTERNATIONAL, INC., et al.,
Defendants.

This matter comes before the Court for construction of a certain limitation from element (a) of Claim 26 from U.S. Patent No. 5,247,434 ("'434 Patent"). Having read and considered the papers submitted, and being fully informed, the Court CONSTRUES this limitation as set forth below.[1]

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[1] The parties requested that the Court resolve this matter without oral argument [Docket No. 295]. After reviewing the papers presented by the parties, the Court finds this matter appropriate for resolution without a hearing.

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity. Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("'434 Patent"); (2) U.S. Patent No. 5,326,476 ("'476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("'131 Patent"); (4) U.S. Patent No. 5,486,286 ("'286 Patent"); and (5) U.S. Patent No. 5,744,027 ("'027 Patent") (collectively "patents-in-suit").

On May 14, 2003, defendants and counter-plaintiffs Baxter International Inc. and Baxter Healthcare Corporation (collectively "Baxter") answered and counterclaimed that Fresenius' hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of the '286 Patent.

Each of the patents-in-suit relates to hemodialysis machines.

A claim construction hearing was held on October 14, 2004 on certain disputed terms. After the Court issued its claim construction ruling on November 22, 2004, the parties met and conferred in order to narrow the selection of additional terms to be construed by the Court.[2]

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[2] The meet and confer was conducted pursuant to the Court's October 8, 2004 Order.

On January 6, 2005, the parties requested that the Court construe one additional claim term: "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration" in Claim 26(a) of the '434 Patent.[3] The parties agree that the claim term-at-issue is a means-plus-function claim.

LEGAL STANDARDS

The first step in construing a means-plus-function claim limitation is to define the particular function of the claim limitation. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 (Fed. Cir. 2001).

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[3] Initially, Baxter contends that Fresenius waived this argument because the parties had originally submitted a joint construction for the claim term-at-issue. The Patent Local Rules were designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed. *See, e.g., Atmel Corp. v. Information Storage Devices*, 1998 U.S. Dist. LEXIS 17564, at *7, 1998 WL 775115 (N.D. Cal. 1998). In this case, however, the joint construction stemmed from a construction first proposed by Fresenius' prior counsel, McDermott, Will & Emery ("MWE"). On May 14, 2004, this Court granted Baxter's motion to disqualify MWE. Subsequently, Fresenius' current counsel, Keker & Van Nest LLP, transitioned into the lead counsel role. Moreover, pursuant to this Court's orders, the parties have met and conferred multiple times over the course of this action in order to reduce the number of disputed terms; it was during one of these supplemental meet and confers that Fresenius notified Baxter of its intention to assert the instant construction of the claim term-at-issue. Given the history of this case, coupled with the efforts of the parties to reduce the number of disputed terms, the Court finds that Fresenius has not waived its right to dispute the construction of the claim term-at-issue.

"The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002).

The next step in construing a means-plus-function claim limitation is to look to the specification and identify the corresponding structure for that function. *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1334 (Fed. Cir. 2004). "Under this second step, 'structure disclosed in the specification is "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003) (quoting *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

DISCUSSION

Claim 26(a) of the '434 Patent calls for:

> A hemodialysis machine comprising:
> (a) *means for controlling a dialysate parameter selected from a group consisting of dialysatetemperature and dialysate concentration*, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer.

See 434.26 (term-at-issue emphasized).[4]

The parties agree on the first step of construction: identifying the recited functions. They are (1) controlling dialysate temperature; and/or (2) controlling dialysate concentration. However, the parties dispute the corresponding structures for those functions, and in particular whether the structures must include an algorithm.

Baxter contends that: (1) the corresponding structure for the control of dialysate temperature is a microprocessor, a heater, and a temperature-sensing device; and (2) the corresponding structure for the control of dialysate concentration is a microprocessor and a concentrate pump. Abernathy Decl., Exh. 10.

Fresenius argues that the corresponding structure for both functions is a heater and temperature sensing device (for temperature) and pump (for concentration) and a microprocessor, operably coupled together, the microprocessor processing an algorithm which allows an operator to change the dialysate temperature or concentration parameters by touching a series of windows and buttons displayed on a touch screen by the microprocessor. *Id.*

In support of its construction, Fresenius argues that because the recited functions require a microprocessor, *WMS Gaming, Inc. v. Int'l Game Tech-*

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[4] The format "XXX.YY" indicates the following: XXX is the patent number; YY is the number of the relevant claim in that patent. This format will be used to identify claims throughout this Order. The format "XXX:YY:ZZ" indicates the following: XXX is the patent number; YY is the relevant column number, and ZZ is the relevant line number. This format will be used to identify specification passages throughout this Order.

nology, 184 F.3d 1339 (Fed. Cir. 1999) compels the Court to review the specification to determine the algorithm disclosed for performing the recited functions, and limit the claim accordingly.

In *WMS Gaming*, the Federal Circuit stated: "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, *programmed to carry out an algorithm*, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *Id.* at 1348-49 (emphasis added); *see Tehrani v. Hamilton Medical, Inc.*, 331 F.3d 1355, 1361-62 (Fed. Cir. 2003) (remanding to the district court to determine the precise algorithm where *both parties and the district court agreed* that the structure referred to by a "means for processing" was "a processor running an algorithm as described in the specification.").

Based on *WMS Gaming*, Fresenius argues that merely because the disclosed structure includes a microprocessor "that implements an algorithm, the structure is limited to the microprocessor performing that specific algorithm." Fres. Supp. Br. at 3. However, Fresenius reads the rule too broadly. The cases cited by Fresenius specifically held that the corresponding structure for the claim limitations at issue *necessarily included* the particular algorithms. *See Metrologic Instruments, Inc. v. PSC, Inc.*, 2004 U.S. Dist. LEXIS 24949, at *40, 2004 WL 2851955 (D.N.J. 2004) (discussing and distinguishing *WMS Gaming* and *Tehrani*); *cf. Anoto AB v. Sekendur*, 2004 U.S. Dist. LEXIS 7950, at *37-38, 2004 WL 1102407 (N.D. Ill. 2004). Here, the corresponding structure(s) do not *necessarily include* the algorithms advanced by Fresenius.

In *WMS Gaming*, the claimed function was "assigning a plurality of numbers to stop positions, where the plurality of numbers exceeds the number of stop positions and some stop positions are represented by more than one number." *Id.* at 1347. *The parties agreed* that the claimed function was performed according to an algorithm and that the corresponding structure needed both a microprocessor and an algorithm. *Id.* at 1348 (emphasis added).

The function of the disputed limitation in *Tehrani* also specified what and how data was manipulated:

> processing data representing at least air viscosity factor in lungs of the patient, barometric pressure, lung elastance factor of the patient and measured levels of carbon dioxide and oxygen levels of the patient, and for providing, based upon said data, digital output data indicative of required ventilation and optimum frequency for a next breath of the patient.
>
> ‘

Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1357 (Fed. Cir. 2003).

The court stated that "[t]he the claims must be construed to require that the device first process the five data values and then use those data values to calculate tidal volume and breath frequency." *Id.* at 1360. Critically, *the parties agreed*, and the court found, "that the structure corresponding to the processing function is the disclosed microprocessor *that is programmed to perform the disclosed algorithm*." *Id.* at 1362 (emphasis added); *see also Metrologic In-*

struments, 2004 U.S. Dist. LEXIS 24949, at *41-42 (distinguishing *Tehrani*).

Here, the construction advanced by Fresenius improperly imports both functional and structural limitations.

With respect to the recited functions, unlike *WMS Gaming* and *Tehrani*, the recited functions of Claim 26(a) do not recite a specific software routine or data manipulation. The explicit claim language of Claim 26(a) does not suggest that the claimed functions include use of a touch screen. To the extent that Fresenius finds the function of using a touch screen in the patent specification, Fresenius cites no authority for importing functional language from the specification into the claim. *See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002); *Creo Prods. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed. Cir. 2002) ("[The Federal Circuit] has repeatedly held that it is improper to restrict a means-plus-function limitation by adopting a function different from that explicitly recited in the claim.").

With respect to the structures corresponding to the functions of Claim 26(a), while the disclosed structures include microprocessors, they do not require that the microprocessor process data that the operator enters using a touch screen. 35 U.S.C. § 112 ¶ 6 does not "permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Asyst Technologies, Inc. v. Empak, Inc.*, 268 F.3d 1364, 1369-70 (Fed. Cir. 2001) (citing *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1257-58 (Fed. Cir. 1999)). "Structural features that do not actually perform the re-

cited function do not constitute corresponding structure and thus do not serve as claim limitations." *Id.* at 1370 (citing *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1308-09 (Fed. Cir. 1998), and *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)) ("[S]tructure disclosed in the specification is only 'corresponding' structure if the specification or prosecution history clearly links or associates that structure to the function recited in the claim."); *see also Faroudja Lab., Inc. v. Dwin Elecs., Inc.*, 76 F. Supp. 2d 999, 1010 (N.D. Cal. 1999) (noting that *WMS Gaming* "does not lead to the conclusion that a court must, as a routine matter, limit the structural element to its functional purpose by importing functional language into the structure specification"); .

Asyst provides a helpful example, corroborating its finding that "it is not necessary to claim in a patent every device required to enable the invention to be used":

> An electrical outlet enables a toaster to work, but the outlet is not for that reason considered part of the toaster. *The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended.*

Asyst, 268 F.3d at 1371 (emphasis added) (citation omitted).

Although Fresenius concedes that the structure includes a microprocessor, a pump and a heater,

it tries to add an algorithm, citing to the specification in support of its construction:

> The microprocessor, using information pertaining to dialysate flow rate and concentrate parameters entered by the machine operator using a touch screen (described in detail hereinbelow), calculates the amount of concentrate necessary to achieve a correct ratio of water and "A" concentrate for hemodialysis therapy. The microprocessor thereby adjusts the angular velocity of the stepper motor.

See 434:2:57-64; Fres. Supp. Br. at 4.

This quote establishes that the microprocessor and the concentrate pump, not the touch screen, "actually perform" the function of controlling dialysate concentration. It is not "necessary" that the data come from the touch screen. The touch screen merely provides data, just like an outlet provides electricity.

Likewise, a microprocessor that "turns 'the heater on and off as required to maintain the water temperature at the proper level'" identifies the structure -- a microprocessor and heater -- which is "necessary to perform" the recited function of controlling dialysate temperature.[5] *See* Fres. Supp. Br. at 5 (citing 434:2:29-43)). Despite this clear statement from the specification, Fresenius contends that the corre-

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[5] The passage that Fresenius cites in support of its proposition that corresponding structure for controlling dialysate temperature requires a touch screen does not mention a microprocessor or a heater. *See* Fres. Supp. Br. at 5.

sponding structure must include an algorithm enabling the microprocessor to determine the "proper level" of water temperature. *Id.* The recited function, however, is controlling dialysate temperature, not controlling dialysate temperature by determining the proper level of water temperature. The language Fresenius attempts to provide structure for is from the specification, not the claim. *Id.*

For both controlling dialysate concentration and controlling dialysate temperature, the touch screen is akin to the "electrical outlet" of *Asyst*, i.e., the touch screen enables the microprocessor, pump and heater to work but is not part of the microprocessor, pump and heater.

In addition to Fresenius' reliance on *WMS Gaming* and *Tehrani*, Fresenius contends that the prosecution history supports its position. However, review of the prosecution history for Claim 26 dictates otherwise. In distinguishing *Kerns*, the prosecuting attorney explicitly argued:

> Claim 51 [which became Claim 26 in the issued patent] has been amended to include, in part (a), means for controlling a parameter of dialysate selected from a group consisting of dialysate temperature and concentration. Kerns et al. provides no hint whatsoever of controlling temperature and concentration of fluids being delivered. *Accomplishing these ends requires components such as a heater* (specification page 2, line 24) *and concentrate pump(s)* (specification page 2, line 24-25 and lines 28-29). Infusion pumps such as disclosed in Kerns et al. do not require such features.

> The Kerns et al. apparatus merely pumps. Therefore, claim 51 is not obvious from Kerns et al.

See Abernathy Reply Decl. Exh. 11 at BA 095364 (Amendment dated January 26, 1993 from the prosecution history of the '434 Patent (emphasis added)).

The prosecuting attorneys did not state that the claim required the use of a touch screen to control dialysate temperature and concentration. Instead, the prosecuting attorneys remarked that components such as a heater and concentrate pump are required to control dialysate temperature and concentration. The prosecution history, therefore, does not support Fresenius' proffered construction. *Cf. Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) ("[F]or prosecution disclaimer to attach, [the Federal Circuit] requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.") (citations omitted).

Neither the cases relied on by Fresenius in support of its position that an algorithm must be included as corresponding structure for the limitation from Claim 26(a), the patent specification, nor the prosecution history, support Fresenius' construction.

CONCLUSION

Accordingly, the claim term "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate

concentration" in Claim 26(a) of the '434 Patent is construed as follows:

1. The Court hereby CONSTRUES the function of "means for controlling a dialysate parameter selected from the group consisting of dialysate temperature and dialysate concentration" as **controlling dialysate temperature and/or controlling dialysate concentration**.
2. The Court hereby CONSTRUES the corresponding structure for the control of dialysate temperature as **requiring a microprocessor, a heater, and a temperature-sensing device**.
3. The Court hereby CONSTRUES the corresponding structure for the control of dialysate concentration as **requiring a microprocessor and a concentrate pump**.

IT IS SO ORDERED.

DATED: March 1, 2005

/s/ Saundra Brown Armstrong
SAUNDRA BROWN ARMSTRONG
United States District Judge

APPENDIX F

CONSTITUTIONAL PROVISION INVOLVED

"In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. Const. amend. VII.

STATUTORY PROVISIONS INVOLVED

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a).

"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6.